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Elaboration of the Optimal Structure of Flat Implants for Hernia Treatments

Abstract
One of the most commonly conducted procedures in general surgery is hernia treatment. This problem concerns approx. 4% of the human population. The factor that significantly lowers the efficacy of the hernia treatment procedure, also called hernioplasty, is the high risk of recurrence, which leads to repeated surgery. The aim of this thesis is to design an optimal surgical mesh structure for hernia treatment with the use of the non-tension method. In order to select an optimal prototype, qualitative analysis of chemical purity, physical properties as well as morphology and pathophysiology were performed. A designated group of quality markers and a general quality marker based on risk analysis acc. PN-EN ISO 14971:2004 Standard allowed to select an optimal hernia mesh prototype

Key words: *harnia, surgical mesh, polypropylene, structure, strength, quality, qualitative analysis, optimisation.*

Introduction

Hernia treatments are one of the most often executed surgical interventions in general surgery. A hernia occurs when some organs or tissue entirely or partly protrude beyond its correct, anatomical position. This phenomenon describes all situations when an organ or tissue bulges and moves, mostly as a consequence of a reduction in the endurance of a body's cavity, mostly the abdominal wall.

The application of a tension-free technique with the use of fascia, artificial prosthesis in the form of so called hernia mesh, has revolutionized the surgical treatment of hernia. The above technique has considerably reduced the quantity of hernia recurrences and made it possible to reconstruct an abdominal hernia, which has a large gate, without many post-operative complications. Presently, more than 1 mln. artificial implants are grafted annually worldwide.

Implants applied during hernioplasty should ideally imitate the parameters (proprieties and dynamics) of the abdominal wall's structures as well as introduce the additional reinforcement of connective tissue (fascia).

However, when designing hernia meshes, one should take into account all aspects connected with both the chemical composition of the medical device and its physical profile.

Surgical mesh implanted into human fascia is subjected to two kinds of forces:

- a force acting parallel to the surface of the implant responsible for simultaneous expansion of the mesh in two basic directions: longitudinal and transversal – tensile strength,
- a force acting perpendicular to the surface of the implant, connected with the influence of intraabdominal pressure on the abdominal wall – bursting strength.

As it has been estimated in many *ex vivo* investigations, the maximum tensile strength of a dog's abdominal wall (muscles and fascia) is 36 ± 17 N/cm, a rabbit's 10 – 25 N/cm [12 – 13], and that of a rat is 11 – 16 N/cm [14 – 15].

Based on the above-mentioned animal experiments as well as post-mortem examinations of the tensile strength of the human abdominal wall, it seems to be rational, taking into account patient safety, to accept a minimal tensile strength of hernia implants of no lower than 100 N/5 cm in width [22].

Lipton et al. [16] and Read [17] estimated a suture pull-out strength for a sutured line after hernioplasty using Bassini's and McVaya's technique. He evaluated the maximum resistance sufficient for the fascia continuity of the suture to remain. In his post-mortem studies, Greenall [18] determined the maximum suture pull out strength, both longitudinal and transversal. Depending on the length of the suture, the pull out strength was appropriately estimated as 17.0 N in the transverse and 8.8 N in the longitudinal incision. The value of 17.0 N can be accepted the consensus among the maximum strength acting on the suture after the implantation and maximum endurance on tearing off the tissues of the abdominal wall.

The abdominal wall and inguinal region - the most frequent locations of hernia- are built from difficult systems of muscle and fascia. Physiological bulges of the abdominal wall at a maximum strength of 16 N/cm fluctuate from 11 % to 40 % [19].

Experimental investigations [20 – 23] showed that the maximum intraabdominal pressure does not exceed the value of 20 kPa, pressure during a cough or pressing – 7.9 kPa, during pain – 5.9 kPa, intraabdominal pressure in the standing position – 1.7 kPa, during limited blood flow – 1.3 kPa and intraabdominal pressure when lying on the back – 0.8 kPa.

The value of the circular bursting strength calculated for both theoretical considerations in the spherical (16 N/cm) [5, 22] or cylindrical model (32 N/cm) [5] is comparable with post-mortem experimental values obtained for human muscular fascia [24 - 26].

Aim

The aim of the study was to evaluate optimal prototypes of hernia mesh taking into account the physical properties, chemical purity as well as pathophysiological behaviour with respect to clinical performance and safety.

Materials and methods

Materials

Sources

Monofilament polypropylene yarns with a linear density weight of 185 dtex, which relates to the thickness from 0.16 mm, were used to manufacture hernia meshes. The material was selected from among 3 types of polypropylene monofilament yarns because of the repeatability of the delivery parameters. The polypropylene sources were characterised by a lack of shrinkage after the activity of water at

40 ± 2 °C (simulating the temperature of the human body) or after steam at 120 ± 2 °C (simulating autoclaving) [26].

Packaging

All the hernia mesh prototypes were sterilised with ethylene oxide (EO) in a validated process, in BOM double pouches of the medical quality (OPM/MEDICAL PACKAGING Ltd., Poland). This type of packaging was adapted to the sterilization using water steam and EO, fulfilling the requirements of Standards PN-EN 868-1:1999 and PN-EN 868-5:2001.

Analytical methods

Chemical purity

An aqueous extract from EO sterilized prototypes of the hernia mesh prototypes was prepared according to Standards PN-P-04894:1984 and PN-EN ISO 10993-12:2005 at 120 °C ± 1 °C for 60 using exhaustive extraction in high-purified water (osmosis, conductivity < 1.5 μS cm) according to Standards PN-EN ISO 10993-18:2005 and PN-EN ISO 10993-12:2005.

Permanganate oxigenicity

The permanganate oxigenicity of the aqueous extract was determined according to Standard PN-P-04896:1984.

UV absorption

The UV absorption of the aqueous extract was determined using Varian Cary 50 UV-Vis-NIR spectrophotometers according to Standard PN-P-04990:1989.

Content of froth-making agents

The content of froth-making agents in the aqueous extract was determined according to Standard PN-P-04781:1989 .

Extractable in ether

The extractable in ether was determined according to Standard PN-83 / P-04607 (method A) by exhausting extraction according to the recommendations of Standards PN-EN ISO 10993-18:2005 and PN-EN ISO 10993-12:2005 .

Estimation of the physical properties of hernia mesh prototypes

Surface weight

The surface weight of the hernia mesh prototypes was determined by Standard PN-P-04891:1983 Standard.

Tensile strength

The tensile strength and elongation at break in the transverse or longitudinal direction of the hernia mesh prototypes was evaluated according to Standard PN-EN ISO 13934-1:2002 . The width of the samples was 5 cm.

Stamp pressure test

A stamp pressure test of the hernia mesh prototypes was carried out according to Standard PN-EN ISO 12236:1998 using a flat or spherical stamp, as described in [3 - 4, 26].

The measurement consisted in the following evaluations:

- bursting strength - in N,
- circulatory bursting strength falling on the stamp contact circuit with the sample at the moment of the breakdown. In the case of a flat stamp, the circuit related to the total circuit of the stamp, as in the case of the spherical stamp, the circuit increased together with the displacement of the stamp.
- dislocation of the spherical stamp at the breakdown or at a circulatory bursting strength of 16 N/cm or 32 N/cm - in mm.

Suture pull-out

The method of pulling the suture out the hernia mesh prototypes was worked out on the basis of Standard ISO 7198:1998 [26]. The maximum strength of the suture pull-out in N and dislocation in mm were recorded.

Thickness

The thickness of the surgical mesh prototypes was estimated according to Standard PN-EN ISO 5084:1994.

Porosity

The porosity, area of pores and pore distribution of the hernia mesh prototypes were determined using ImageJ v 1.34 software [6 - 7, 26] according to a procedure worked out at TRICOMED SA. [8, 26]. The porosity was expressed as a coefficient of porosity defined as the relation of the total pore surface in a given prototype of hernia mesh to the total surface of the hernia mesh.

Elaboration of general (GCQ) and sectional coefficients of quality (SCQ) for the prototypes of hernia mesh

Criterial markers were chosen with respect to their significance regarding the safety and performance of the projected hernia meshes, based on the risk analysis according to Standard PN-EN ISO 14971:2004.

The above mentioned used parameters are described by different units, and therefore it is convenient to used relative coefficient for describing the particular features; these coefficients are called criterial markers (x_i) and are calculated according to [9, 26].

Values k_{min} and k_{max} were marked-assessed on the basis of the parameters of equivalent medical devices, using well-known and documentary evidence of their clinical use: Prolene®, Vypro®, Herniamesh™, Hertra™, Mersilene®, Atrium®, Dallop® R-11, Dallop® R-13, Dallop® PP TMS, Dallop® PP JS, Dallop® PP TDM, Duramesh™, Tecnomesh™, Dynamesh™ PP. The criterial marks assigned did not possess equal validity, mainly because of the target proprieties of hernia meshes.

Sectional coefficients of quality (SCQ) and the General coefficient of quality (GCQ) were estimated according to Żyliński [8 - 9, 26].

The range of the general coefficient of quality (GCQ) and sectional coefficients of quality (SCQs) of the prototypes were in range of 0 to 1, where 1 represents the ideal quality – perfection.

The coefficients of quality are graphically presented in the form of a circular graph, where radial vectors show the values of individual SCQs in the background of the circle with a radius equal to the maximum value of the quality coefficient. the surfaces of segments of the circle indicate mutual proportions among the SCQ values.

The quality coefficients calculated were classified into a suitable quality class (K), where K = 0 and K = 9 - very unfavorable [9, 26].

Design of hernia mesh prototypes

The hernia mesh prototypes were designed with strong pressure at suitable locations of the stages, assuring an effective way of purifying semi-finished products from chemical, physical and microbiological contamination as well as assuring process repeatability. The warping process was carried out on a DS14PW sectional warping machine (Karl Mayer, Germany). All variants of flat knits were produced on a RM6F Rachel knitting machine (Karl Mayer, Germany), gauge number - 32 and working width - 75”.

Five variants of knits were produced, differing in stitches or stitch density. The variants are described in detail in ***Table 1***.

The process of purification was aimed at reducing the content of physical and chemical contamination. It was carried out in a thread washer at 40 °C for 30 min. Each batch was washed twice with purified water.

Initially purified knits were subjected to a stabilization/drying process using a FAMATEX stabilisation machine at 138 °C, for 30 s. The main stabilisation was carried out in frame boxes on the the laboratory stabilisation machine (Benz, Germany) at 154 °C or 163 °C for 150 s or 180 s, respectively. The process was conducted in an autoclave with high purified water at 121 °C for 60 min. Then the knits were cooled to 80 °C and washed with high-purified water several times. The autoclaving and washing operations with high-purified water was repeated. The semi-finished products were finally dried in an oven in clean, aseptic air (ISO Class 7) at 60 °C. The mechanical cut of the hernia mesh prototypes caused the formation of irregular, sharp edges which can, after the implantation, mechanically irritate surrounding tissue. Thermal process cutting was introduced, providing safe cutting of the hernia mesh prototypes with the use of a modified pulse welder. This process deemed suitable for the safe finish of the edges of all prototypes. The hernia mesh prototypes were packed in the monitored zone of a clean ISO class 7 to avoid additional microbiological cross-contamination. The Packaging was welded using a continuous welder (type ZFP-15, TZMO S.A., Poland).

A sterilization process was carried out using ethylene oxide (EO) in a validated condition according to Standard PN-EN 550:2002. EO sterilisation was monitored due to the formation of EO residue or its derivative, according to Standard PN-EN ISO 10993-7:2005.

Table 1. *Elaborated designs of knits for surgical meshes with manufacturing parameters and prototype characteristics; Number of threads in the warp for all mash types (I - 59 × 10 spool 8", II - 59 × 10 spool 8"); [1)] - determined for prototypes after EO sterilization. Number of course (C) and wale1 repeats (W).*

Type	Parameters of the knitting process	C	W
DALLOP MT	- threading of guide bars I 1 * II 1 * - pattern chain notation I 42/46/20/24/20/46 II II 24/20/46/42/46/20 II Warp take-up I : II - 1 : 1.	25	34
DALLOP MS	- threading of guide bars I 1 * II * 1 - pattern chain notation I 20/42/68/46 II II 20/42/68/46 II Warp take-up I : II - 1: 1.	34	70
DALLOP MA	- threading of guide bars I 1 * II * 1 - pattern chain notation I 46/24/20/42 II II 46/24/20/42 II Warp take-up I : II - 1: 1.	32	65
DALLOP MJ	- threading of guide bars I 1 * II * 1 - pattern chain notation I 20/24 II II 20/24 II Warp take-up I : II - 1: 1	58	84
DALLOP MTX	- threading of guide bars I 1 * II 1 * - pattern chain notation I 42/46/20/24/20/46 II II 24/20/46/42/46/20 II Warp take-up I : II - 1: 1	15	34

Results and discussion

Estimation of physical properties of the hernia mesh prototypes

Figures 1 - 4 show the results of the parameters of the physical prototypes of the surgical meshes introduced.

All the prototypes prepared were characterised by an indispensable circular bursting strength (> 32 N/cm of circuit), taking into account their clinical use, a tensile strength in the longitudinal and transverse directions (> 100 N) and a thickness lower than 1.00 mm (in range of 0.48 mm for the DALLOP MJ prototype to 0.76 mm for the DALLOP MTX prototype). Unfortunately, the DALLOP MJ prototype did not show any shape memory, and it was characterised by a low tensile strength (170 N in the longitudinal direction; 140 N in the transverse direction). The DALLOP MS prototype possessed the highest surface weight (about 10% higher than other prototypes). The circular bursting strength of the prototypes ranged from 50.3 N/cm (DALLOP MA) to 76.8 N/cm (DALLOP MS), whereas the tensile strength in the transverse direction ranged from 130 N (DALLOP MTX) to 371 N (DALLOP MS), and in the longitudinal direction from 170 N (DALLOP MJ) to 361 N (DALLOP MT).

The porosity and coefficient of porosity of the designed prototypes of hernia mesh are presented in ***Table 2***, whereas their distribution of pores is shown in ***Figures 5***.

All the prototypes (***Figure 5.a, b, c, d, e***) of surgical mesh indicated a porosity coefficient higher than 50%. The maximum surface of a single pore yielded from 0.49 mm^2 (for the DALLOP MS prototype) to 7.07 mm^2 (for the DALLOP MTX prototype). The DALLOP MS prototype showed, distinct from the other elaborated prototypes, four maxima of

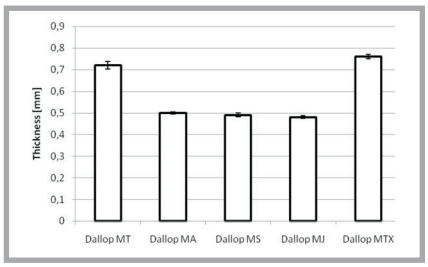

Figure 1. *Thickness of elaborated hernia meshes.*

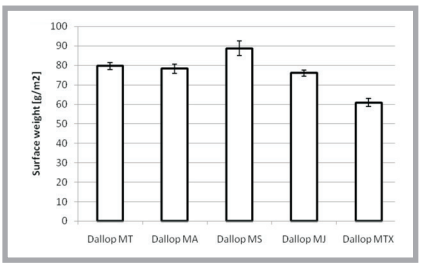

Figure 2. *Surface weight of elaborated hernia meshes.*

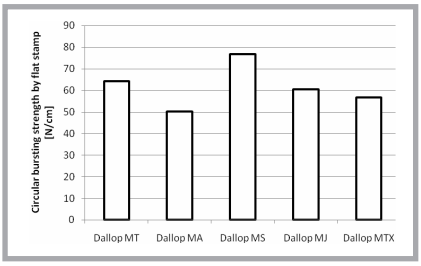

Figure 3. *Circular bursting strength of the hernia meshes, elaborated using a flat stamp (circuit of contact with the hernia mesh prototype is 32.4 cm).*

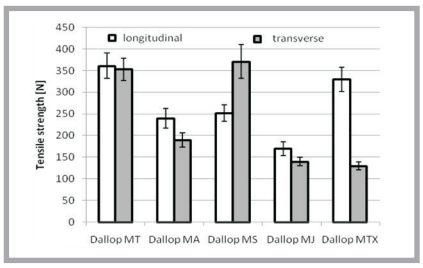

Figure 4. *Tensile strength of elaborated hernia meshes (test sample with at width of 5 cm).*

the pore surface (0.045 mm^2, 0.09 mm^2, 0.17 mm^2 and 0.58 mm^2, respectively; porosity coefficient – 51.3 %). The DALLOP MJ and DALLOP MA prototypes indicated two maxima: 0.08 mm^2 and 0.49 mm^2; porosity coefficient – 52.5% for the DALLOP MJ prototype and 0.12 mm^2 and 0.55 mm^2; porosity coefficient – 50.3% for the DALLOP MA prototype.

The highest area of pores was found for the DALLOP MTX prototype (7.07 mm^2). Its porosity coefficient was the highest from among all the hernia meshes designed (68.4%). The DALLOP MT prototype, being a modification of the DALLOP MTX prototype with an increase in the stitch density, showed an area of pore of 3.3 mm^2 and porosity coefficient of 57.5%. The lowest porosity coefficient (50.3%) was determined for the DALLOP MA prototype. Two groups of prototypes were selected characterized by the surface of their pores: 0.5 mm^2 – 0.8 mm^2 (DALLOP MA, DALLOP MJ, DALLOP MS – variants differing in stitches) and above 3 mm^2 (DALLOP MT and DALLOP MTX – variants differing in stitch density).

Table 2. *Porosity and distribution of pores in the prototypes of hernia mesh.*

Prototype	Estimated range of the surface, mm^2	Average numerical pore surface, mm^2	Coefficient of porosity, %	Total pore surface, %
Dallop MT	0.0 – 0.3 2.6 – 3.6 *0.0 – 0.08*	0.03 ± 0.03 3.30 ± 0.13 *0.03 ± 0.03*	1.6 55.9 *1.4*	57.5
Dallop MS	0.0 – 0.3 0.3 – 0.9 *0.0 – 0.08*	0.09 ± 0.08 0.58 ± 0.09 *0.03 ± 0.02*	6.50 44.8 *1.0*	51.3
Dallop MA	0.0 – 0.3 0.3 – 0.9 *0.0 – 0.08*	0.12 ± 0.11 0.55 ± 0.05 *0.03 ± 0.01*	5.9 44.4 *0.5*	50.3
Dallop MJ	0.0 – 0.3 0.3 – 0.9 *0.0 – 0.08*	0.08 ± 0.03 0.49 ± 0.05 *0.06 ± 0.06*	6.9 45.6 *1.9*	52.5
Dallop MTX	0.0 – 0.3 6.0 – 8.0 *0.0 – 0.08*	0.07 ± 0.07 7.07 ± 0.23 *0.03 ± 0.02*	4.2 64.2 *1.0*	68.4

Estimation of sectional coefficients of quality for the physical properties (SCQ_{Ph}) of hernia mesh prototypes

Table 3 presents the preliminary selection of the prototypes of hernia mesh for the estimation of sectional coefficients of quality (SCQ_{Ph}), taking into account the following physical properties:

- thickness (validity – 1),
- surface weight (validity – 2),
- circular bursting strength (validity – 3),
- tensile strength in the longitudinal direction (validity – 1),
- circular bursting strength in the transverse direction (validity – 1),
- pore surface (validity – 3),
- porosity coefficient (validity – 2).

The best usable properties, based on the physical parameters estimated by SCQ_{Ph}, were found for the DALLOP MTX prototype (SCQ_{Ph} = 0.69; K = 3). The

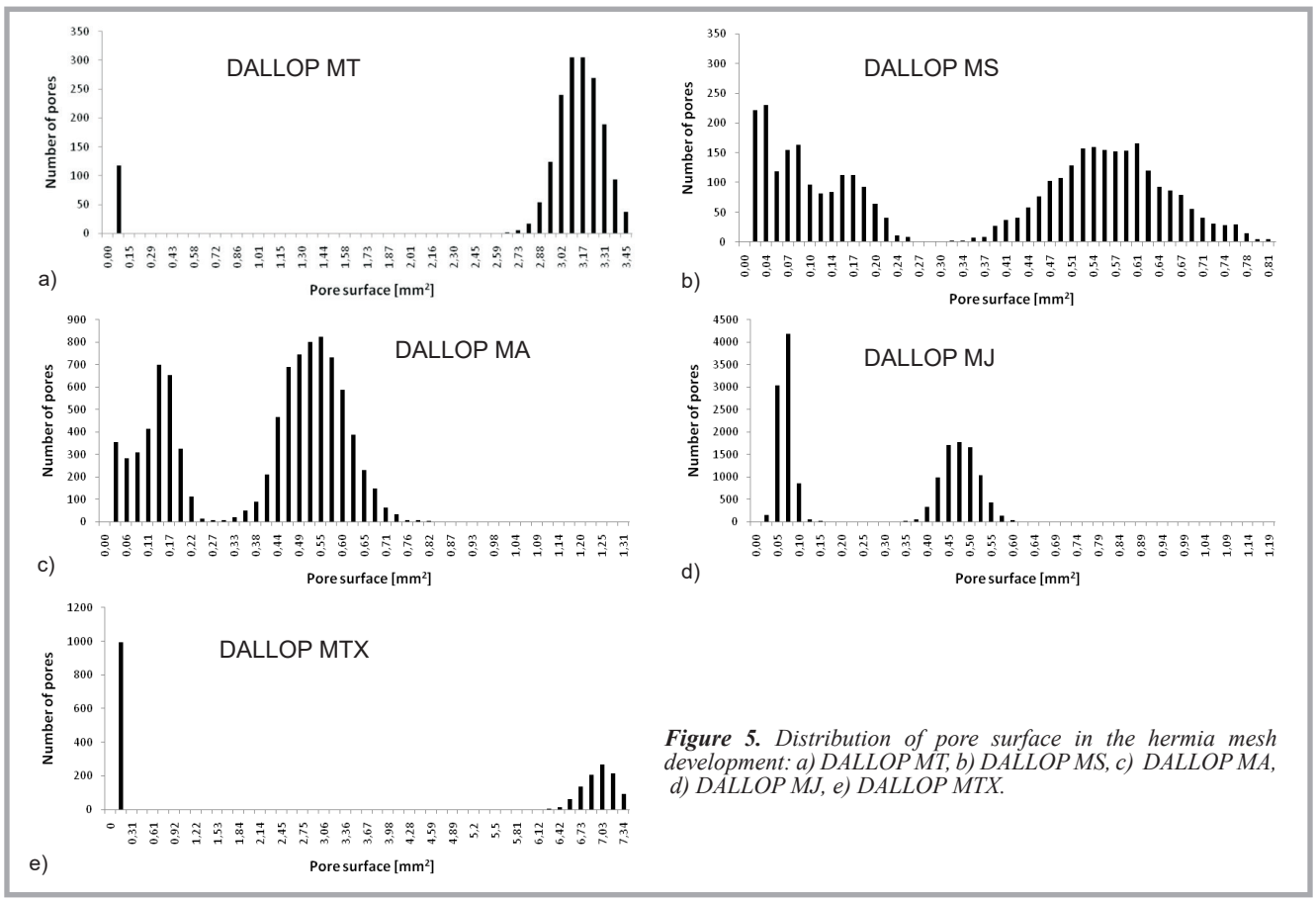

Figure 5. *Distribution of pore surface in the hermia mesh development: a) DALLOP MT, b) DALLOP MS, c) DALLOP MA, d) DALLOP MJ, e) DALLOP MTX.*

Table 3. Selection of hernia mesh prototypes in relation to their physical proprieties – estimation of SCQ_{Ph}; 1) The range of sectional coefficients of quality (SCQs) of prototypes contains in range from 0 to 1 where 1 marks the ideal quality – perfection; 2) K = 0 – meanwhile and K = 9 - very unfavorable.

Prototype	Thickness	Surface weight	Circular bursting strength by flat stamp	Tensile strength in the longitudinal direction	Tensile strength in the transverse direction	Maximal numerical pore surface	Coefficient of porosity	Sectional coefficients of quality for physical properties (SCQ_{Ph}) 1)	Quality class (K) 2)
Validity	1	2	3	1	1	3	2		
Dallop MT	0.40	0.75	0.62	0.42	0.51	0.45	0.74	0.60	4
Dallop MA	0.71	0.76	0.42	0.25	0.18	0.06	0.53	0.43	5
Dallop MS	0.73	0.70	0.80	0.27	0.55	0.05	0.59	0.55	4
Dallop MJ	0.74	0.77	0.56	0.15	0.08	0.08	0.59	0.47	5
Dallop MTX	0.34	0.85	0.51	0.38	0.06	1.00	1.00	0.69	3

DALLOP MT prototype, being a variant of the DALLOP MTX (prototypes differing in the density of stitch only), showed SCQ_{Ph} = 0.60 and K = 4. Among the prototypes characterised by the lowest surface of pores and the lowest porosity coefficient (DALLOP MA, DALLOP MJ, DALLOP MS), the highest SCQ_{Ph} was found for the DALLOP MS prototype (SCQ_{Ph} = 0.55; K = 4). Other hernia mesh prototypes (DALLOP MJ and DALLOP MA) showed SCQ_{Ph} = 0.47 and 0.43, respectively (both K = 5).
Moreover, the SCQ_{Ph} determined for equivalent hernia meshes ranged from 0.35 (Atrium® or Dallop® PP JS hernia meshes) to 0.60 (Prolene® hernia mesh).

Estimation of the chemical purity of the hernia mesh prototypes

Chemical purity was estimated taking into account the requirements of Standards PN-EN ISO 10993-18:2005 and PN-EN ISO 10993-12:2005 . The results of quantitative and qualitative analyzes of extracts in polar or apolar solvents are shown in ***Figures 6 - 8***.

Aqueous extracts made in 120 °C for 60 min (exhaustive extraction) for all prototypes were characterised by high chemical purity, both quantitatively and qualitatively. The aqueous extract of all the hernia meshes did not have any froth-making agents.

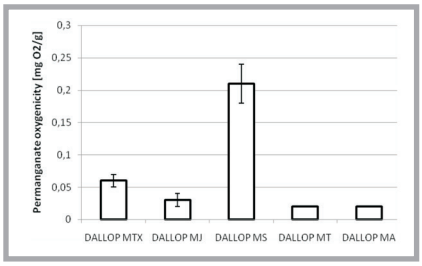

Figure 6. *Permanganate oxygenicity of the aqueous extract of the elaborated hernia mesh.*

A significantly low contamination content, extractable in ether, was determined for the prototypes. The minimum content of extractable contamination was determined for DALLOP MJ (0.07%) as well as the maximum for DALLOP MT (0.12%). There were no differences in UV absorption between aqueous extracts from the prototypes and those for repetitions. Only the aqueous extract from the DALLOP MS prototype showed an increase in permanganate oxygenate in comparison with other prototypes of hernia mesh. The differences determined were directly connected with the type of stitch, mostly with the number of pores, statistically occurring in the highest percentage (7.5% of prototype surface consist in pores having surface below 150 μm2).

Estimation of sectional coefficients of quality for the chemical purity (SCQ_{Ch}) of the hernia mesh prototypes

Table 4 presents the preliminary selection of the prototypes of hernia mesh for estimation of sectional coefficients of quality (SCQ_{Ch}) taking into account the following chemical purity:

- UV absorption at λ = 245 nm (validity – 1) see ***Figure 7***,
- UV absorption at λ = 230 nm (validity – 1) see ***Figure 7***,
- Permanganate oxygenate (validity – 3) see ***Figure 6***,
- Content of froth-making agents (validity – 2) see ***Figure 6,***
- Extractable in ether (validity – 3) see ***Figure 8***.

All the prototypes of hernia mesh were characterised by a high SCQ_{Ch}, above 0.86. The lowest SCQ_{Ch} was determined for the DALLOP MJ and DALLOP MS prototypes (SCQ_{Ch} = 0.93 and SCQ_{Ch} = 0.86, respectively). The DALLOP MTX prototype showed SCQ_{Ch} = 0.95, whereas DALLOP MA and DALLOP MT showed the highest SCQ_{Ch} = 0.97. Above the SCQ_{Ch} yielded in the very high class of the quality K = 0 for the majority of the prototypes of hernia mesh taking into account chemical purity.

In the case of equivalent medical devices, the lowest SCQ_{Ch} (0.08) was found for Tecnomesh™ hernia mesh, whereas the highest SCQ_{Ch} = (0.86) was for Dallop® PP family hernia meshes.

Estimation of the pathophysiological behaviour of the hernia mesh prototypes

The pathophysiological properties of the hernia mesh prototypes were elaborated in relation to the critical mechanical properties simulating clinical use, such as:

- suture pull-out resistance,
- circular bursting strength using a spherical stamp,
- dislocation
  - at bursting or

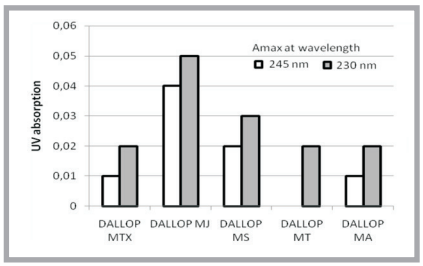

Figure 7. *UV absorption of the aqueous extract of the hernia mesh elaborated.*

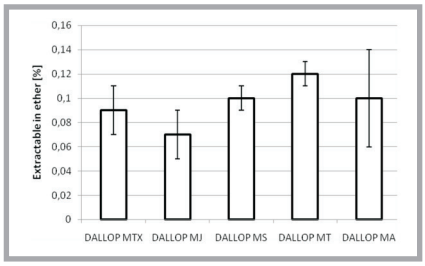

Figure 8. *Extractable in ether extract of the aqueous extract of the hernia mesh elaborated.*

Table 4. Selection of hernia mesh prototypes in relation to their chemical purity – estimation of SCQ_{Ch}; 1) The range of sectional coefficients of quality (SCQs) of prototypes contains in range from 0 to 1 where 1 marks the ideal quality – perfection; 2) K = 0 – meanwhile and K = 9 - very unfavorable.

Prototype	Absorption at λ = 245 nm	Absorption at λ = 230 nm	Permanganate oxygenate	Froth-making agents content	Extractable in ether	Sectional coefficients of quality for chemical purity (SCQ_{Ch}) 1)	Quality class (K) 2)
Validity	1	1	3	2	3		
Dallop MT	1.00	0.95	1.00	1.00	0.91	0.97	0
Dallop MA	0.90	0.95	1.00	1.00	0.94	0.97	0
Dallop MS	0.80	0.89	0.68	1.00	0.94	0.86	1
Dallop MJ	0.60	0.79	0.98	1.00	1.00	0.93	0
Dallop MTX	0.90	0.95	0.93	1.00	0.96	0.95	0

- at 16 N/cm (minimum bursting resistance after implantation) or
- at 32 N/cm (optimum bursting resistance after implantation).

The results of pathophysiological mechanical properties of the hernia meshes are presented in ***Figures 9 – 11***.

All the evaluated prototypes fulfilled the criteria which were connected with the minimum strength of pulling out the sutures (17 N), the relative bursting strength

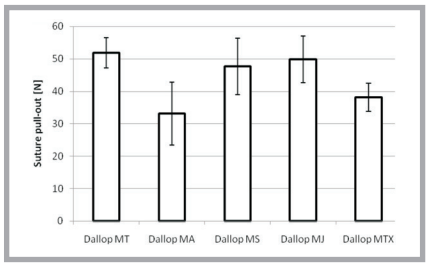

Figure 13. *Suture pull-out of elaborated hernia meshes.*

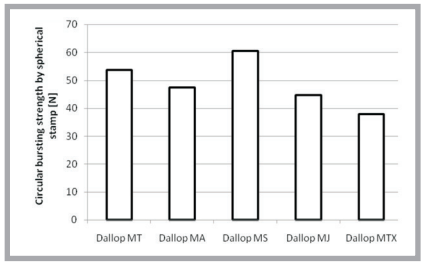

Figure 14. *Circular bursting strength by spherical stamp of elaborated hernia meshes.*

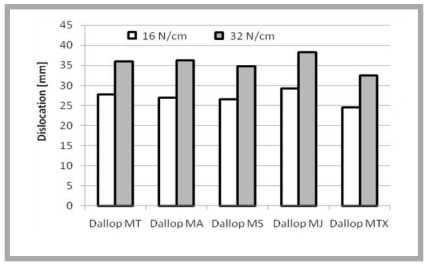

Figure 15. *Dislocation at bursting strength of 16 or 32 N/cm of hernia meshes during the spherical stamp pressure test.*

per a circumference length unit (32 N/cm), and the displacement of the object tested at a circumference force of 16 N/cm and 32 N/cm. In the case of dislocation, it should not be higher than 40 mm, as described in literature [11].

The highest circular bursting strength achieved using the spherical stamp was noted for the DALLOP MS prototype (60.4 N/cm), characterized by the highest surface weight. The circular bursting strength of the DALLOP MTX prototype (37.9 N/cm), despite its synthetic material being reduced by 25% and an increase in the maximal surface of the pores by approx. 100% in relation to the DALLOP MT prototype, was sufficient to assure the resistance of the implant designed against intraabdominal pressure. The remaining prototypes of hernia mesh showed a circular bursting strength of between 44.7 N/cm (DALLOP MJ) and 47.4 N/cm (DALLOP MA). The design of all the prototypes assessed possessed a resistance against circular bursting strength, indispensable for clinical use in treatment for abdominal defects.

The pull-out strength of sutures from the hernia mesh prototypes yielded from 33.1 N (DALLOP MA) to 51.9 N (DALLOP MT). The lowest of the abovementioned parameter was for prototype DALLOP MA (33.1 N). However, it was almost twice larger than required (17 N). The dislocation, both at a bursting strength of 16 N/cm and 32 N/cm, was noted as below the limit of physiological requirements for the structures of the abdominal wall (40 mm) [11].

Estimation of sectional coefficients of quality for the pathophysiological behaviour (SCQ_{PPh}) of the hernia mesh prototypes

Table 5 (see page 108) presents a criteria selection of the hernia mesh prototypes, taking into account pathophysiological behaviour and calculated sectional coefficients of quality for the pathophysiological behaviour (SCQ_{PPh}) in the range of the following parameters:

- suture pull-out strength (validity – 2),
- circular bursting strength using a spherical stamp (validity – 3),
- dislocation at 16 N/cm (validity – 1),
- dislocation at 32 N/cm (validity – 3).

The highest SCQ_{PPh} was found for the DALLOP MT and DALLOP MJ prototypes (SCQ_{PPh} = 0.66; K = 3) then the DALLOP MS prototype (SCQ_{PPh} = 0.64; K = 3), DALLOP MA (SCQ_{PPh} = 0.53; K = 4) and finally DALLOP MTX (SCQ_{PPh} = 0.44; K = 5).

Estimation of the general coefficient of quality (GCQ)

The general coefficient of quality (GCQ) elaborated for the physical properties, chemical purity and pathophysiological behavior showed that the DALLOP MT prototype of hernia mesh had the best value (GCQ = 0.74; K = 2), then DALLOP MTX (GCQ = 0.69; K = 3), DALLOP MJ and DALLOP MS (GCQ = 0.67; K = 3) and finally DALLOP MA (GCQ = 0.64; K = 3). Assumptions for the SCQs and GCQ results are presented in ***Table 6*** (see page 108).

It is necessary to take into account that the best commercial hernia meshes, estimated according to the same criteria, were in a quality class no better than 5 – "average" (Dallop® PP TDM or Prolene® hernia meshes).

Conclusion

All the prototypes of hernia mesh designed demonstrate suitable properties in regard to the potential range of their application [27, 28], such as the chemical purity and mechanical profile. Moreover, as shown in ***Table 6***, the maximum estimation of the quality sectional coefficients for the chemical purity, physical properties and pathophysiological behaviour led to the conclusion that the DALLOP MT proto-

Table 5. *Selection of hernia mesh prototypes in relation to their pathophysiological behaviour – estimation of SCQ_{PPh}; [1] The range of sectional coefficients of quality (SCQs) of prototypes contains in range from 0 to 1 where 1 marks the ideal quality – perfection; [2] K = 0 – meanwhile and K = 9 - very unfavorable.*

Prototype	Suture pull-out	Circular bursting strength by spherical stamp	Dislocation at bursting strength of 16 N/cm	Dislocation at bursting strength of 32 N/cm	Sectional coefficients of quality for pathophysiological behaviour (SCQ_{PPh}) [1]	Quality class (K) [2]
Validity	2	3	1	3		
Dallop MT	0.81	0.50	0.39	0.80	0.66	3
Dallop MA	0.37	0.42	0.35	0.81	0.53	4
Dallop MS	0.71	0.59	0.33	0.74	0.64	3
Dallop MJ	0.76	0.38	0.46	0.93	0.66	3
Dallop MTX	0.49	0.29	0.23	0.63	0.44	5

type of hernia mesh is distinguished by its optimum usable parameters, especially due to the suitable forcing at high porosity and the minimisation of the surface weight, maintaining mechanical resistance against intraabdominal pressure. DALLOP MT prototype of hernia mesh has been CE-certificated and is commercially offered as the OPTOMESHTM Macropore Hernia Mesh.

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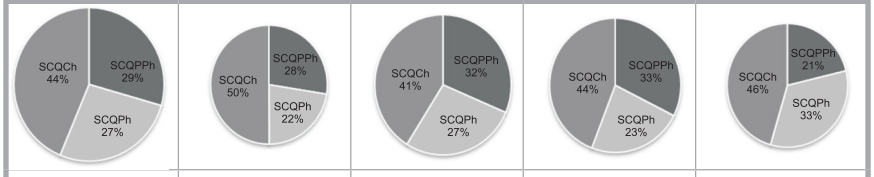
Table 6. *Sectional coefficients of quality (SCQs) for the physical properties, chemical purity, pathophysiological behaviour and general coefficient of quality (GCQ) estimated for the hernia meshes prototypes; [1] The range of sectional coefficients of quality (SCQs) and general coefficient of quality (GCQ) of prototypes contains in range from 0 to 1 where 1 marks the ideal quality – perfection; [2] K = 0 – meanwhile and K = 9 - very unfavorable, [3] Coefficients of quality have been graphically presented in the form of circular graph where radial vectors show the values of individual SCQs to background of the circle with radius of the quality coefficient maximum value and the segments surfaces of circle indicate mutual proportions among the values of SCQs.*

Prototype	SCQ_{Ph} [1]	K_{Ph}	SCQ_{Ch} [1]	K_{Ch}	SCQ_{PPh} [1]	K_{PPh}	GCQ [1]	K [2]
Dallop MT	0.60	4	0.97	0	0.66	3	0.74	2
Dallop MA	0.43	5	0.97	0	0.53	4	0.64	3
Dallop MS	0.55	4	0.83	1	0.64	3	0.67	3
Dallop MJ	0.47	5	0.89	1	0.66	3	0.67	3
Dallop MTX	0.69	3	0.95	0	0.44	5	0.69	3

Circular graph of quality structure [3]



Dallop MT | Dallop MA | Dallop MS | Dallop MJ | Dallop MTX

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