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Ultra-Light Knitted Structures for Application in Urologinecology and General Surgery – Optimisation of Structure in the Aspect of Physical Parameters

Abstract
The biomimetic properties of implants are the most important aspects of their long-term clinical performance and safety. The gynecological as well as general surgery procedures of soft tissue defect reconstructions require the use of implantable medical devices of more sophisticated complex mechanical features. The aim of the study was to evaluate an optimal (taking into account implantation localisations) structure for knitted implantable medical devices for potential use in gynecological reconstructions, such as vaginal wall reconstructions and urinary incontinence treatment, as well as in general surgery for hernia treatment, in both standard and less-invasive procedures. The study shows a selection of the most optimal knitted structures based on mechanical criteria and further anatomical localisation of the implants designed. The choice of the selection criteria was carried out based on risk analysis according to Standard EN ISO 14971:2009. The idea of the research was to elaborate knitted three dimensional structures of an enhanced one-side surface for better connective tissue incorporation as well as a reduction in the surface mass while retaining the mechanical strength, taking into account anatomical requirements.

Key words: *urologinecology implants, general surgery implants, ultra-light knitted structres, structure optimisation.*

Introduction

vaginal wall reconstruction consists in the execution of surgical procedures correcting the muscular structures and surrounding connective tissue in the vaginal grounds. Damage to vaginal tissue structures can be the after-effect of childbirth, often because of surgery, heavy physical work and/or the loss of the elasticity of structures of the vagina resulting from age (postmenopausal cycle). In the USA and Europe over 6 million serious vaginal prolapses (*colpoptosia*) are diagnosed annually. It is estimated that the quantity of vaginal reconstruction procedures will grow significantly in the USA and Europe, from approx. 400 000 in 2005 to 3 million in coming years [1].

Hernia treatment is one of the procedures most often carried out in the world in general surgery. A hernia is the qualification of a state where some organ tissue, wholly or partly, changes its position in relation to the correct, anatomical one. The millions of inguinal hernia surgeries performed every year in the whole world (only in the USA at least 990 000) are a significant problem, not only from the medical but also from an economic point of view. There is still a demand for more and more new procedures, new designs of medical devices for hernioplasty, continuous investigations on the causes of inguinal hernia formation and scar hernias as well as on the failures of reconstruction procedures [2 - 9].

Urinary incontinence (UI) occurs in 27.6% of women, with most cases (33%) taking place in the 5th decade of a women's life. UI also has a high economic aspect. It has been stated that expense connected with the necessity of the purchase of indispensable medicines (drugs and pharmaceutics or para-pharmaceutics) and disposable hygiene products comprised about 64% of the outlay of healthy women. It was calculated that in the USA the annual direct costs for UI treatment were comparable and similar to those relating to several social diseases, such as breast cancer, osteoporosis or ponds inflammation [10 - 14].

Ex vivo studies showed that the maximal tensile strength of an animal's abdominal wall is within the range of 36 ± 17 N (dogs), 10 – 25 N (rabbits) [15, 16] or 11 – 16 N (rats) [17, 18]. Similar results were obtained for the human abdominal wall in post-mortem studies. However, differences between the values in the vertical and longitudinal directions did not exceed 40%.

The most critical parameter in reconstruction procedures is the suture pull-out strength, because the breaking of implants occurs most frequently in the suture line [19]. The safe value of the suture pull-out strength should exceed 10 N, which corresponds with the maximal value of tensile strength detected for human fascia [20].

Taking into consideration Laplace's law, the maximal bursting strength acting on the implant is no higher than 16 N per cm of the circumference**.** However, the experimental results [5, 21 - 23] indicated that the intra-abdominal pressure does not exceed 20 kPa**,** whereas the intra-abdominal pressure during coughing or pressing amounts to 7.9 kPa, during pain – 5.9 kPa, intra-abdominal pressure in the standing position – 1.7 kPa, during limited blood flow – 1.3 kPa and intra-abdominal pressure when lying on the back – 0.8 kPa [5, 21 - 23].

The physiological bulge of the abdominal and vaginal wall at a bursting strength of 16 N per cm of the circumference should not exceed 40% [6].

The implantable medical devices currently used in clinical applications for the medical cases mentioned above are characterised by a significantly higher mechanical strength above the anatomical requirements and, in consequence, by the absence of biomimetic behaviour.

They are made in the form of flat knitted fabrics using high diameter monofilaments (either polypropylene or polyvinylidene fluoride) which induce an acute and chronic inflammatory reaction

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affecting thick scar formation, long-term complications (such as dysfunctions, stiffness of surrounding tissue structures, recurrences, fistula formation, adhesion, etc.) and patient discomfort.

This study presents an optimisation process for knitted structures based on mechanical properties, taking into account the anatomical localisation of the implants designed as well as their future performance and clinical safety.

The optimisation was carried out on the basis of a research programme developed according to the risk analysis given in Standard EN ISO 14971:2009 – the main and optimal tool for an effective design process of medical devices [24].

The purpose of this research was to elaborate three dimensional knitted structures with an enhanced one-side surface for the better incorporation of connective tissue, reduction in the surface mass while retaining the mechanical strength, taking into account the anatomical requirements as well as the reduction in the inflammatory reaction due to the application of monofilaments with a diameter as low as possible.

Materials

The polypropylene monofilament yarn of 0.08 mm diameter (46 dtex) used in this research was made of polypropylene class VI polymer according to US Pharmacopeia (approved for implantation application). The low diameter of the yarn created a low surface of implant contact with surrounding connective tissue, causing relatively low acute and chronic inflammation to avoid massive fibrosis (massive scar formation) [5, 25].

The idea of the monofilament application mentioned above was related to the use of a yarn diameter as low as possible considering the anatomical parameters (mostly mechanical properties) required and the reduction in inflammations due to the lowest surface contact of the implant with surrounding tissue.

The basic parameters of the monofilament are shown in ***Table 1***.

The linear density of the polypropylene monofilament was determined according to Standard PN-EN 13392:2002, the breaking load, tenacity and elongation according to Standard PN-EN 13895:2005, and the shrinkage of monofilament at a temperature of 36 °C and 120 °C was determined according to Standard PN-EN 13844:2005. The temperatures of the shrinkage behaviour were selected to simulate the behaviour of yarn in the human body (36 °C) and during steam sterilisation (120 °C), which is the method of implant sterilisation anticipated.

Methods

Manufacture of variants of implantable medical devices

Variants of 3-D textile structures were manufactured by the knitting technique (using a HKS3M knitting machine, Karl Mayer/Germany). The knitting machine was equipped with a dual needle system with a density of 28 E. The weaves of the knitting fabrics were designed to obtain a 3-D structure (in the form of 4 mm non-regular loops protruding from the flat fabric) that would induce a better, one-side only implant fixation with connective tissue after implantation. The protruding loops were formed during the knitting process as a result of stitches dropping from some of the knitting needles [28]. Seven variants of 3-D knitted fabrics differing in the type of weave (three weave variants: SP1, SP2 and SP3) and some variants differing in the size of the loops were designed for the optimisation of implants for the reconstruction of a vaginal wall and hernia treatment.

The auxiliary agents applied on the yarn to facilitate its processing in the warp-knitting machine were removed by triple washing in purified water (without any surfactants) at a temperature of 30 °C for 15 min. in an ARISTON washing machine. The stabilisation/drying process was carried out in laboratory conditions using a tunnel stabiliser (PONMAT/Poland) at a temperature of 152 °C for a time of 1 min. 45 s while moving the warp-knitted fabric through the stabilising chamber with constant velocity.

In the case of implants for urinary incontinence treatment, five variants of 3-D knitted slings based on a similar weave (SP5) were designed. The removing process of auxiliary agents was carried out in a similar fashion to that described above. Stabilisation was carried out on two plates of the stabilisation device, one of which was a heating plate. The purified slings were fed with constant velocity through a thin slot between the plates. The temperature of the heating plate was set within the range of 145 – 165 °C with approximately 5 °C intervals for each of the variants elaborated. The width of the final slings was 10 ± 1 mm.

All variants of 3-D knitted structures were processed in an autoclave at 121 °C for 30 min to simulate the steam sterilisation process anticipated before the determination of their physical properties.

The parameters of the knitting process, both for the implants for hernia treatments and gynecological applications as well as slings for urinary treatments, are shown in ***Table 2*** (see page 94).

Analytical methods

3-D knitted variants for hernia treatment or gynecological reconstructions

The mechanical parameters, which are the basis for selection of an optimal variant of a 3-D knitted structure, were selected during risk analysis taking into account the most critical hazards and the review of early and long-term clinical complications in vagina wall reconstructions and hernia treatments, both standard and less-invasive [24, 28].

The risk analysis of the 3-D knitted variants for hernia or gynecological reconstructions indicates the necessity of verifying the following: the surface weight, thickness, the tensile strength and elongation at break in both directions, the suture pull-out strength in both directions and on the corner, and the bursting strength and bursting pressure determined by the following two methods: using a semi-spherical stamp simulating the curvature of the abdomen and the air-pressure method.

Surface mass

The surface mass was determined according to Standard PN-EN 12127:2000.

Table 1. *Basic parameters of the polypropylene monofilament yarn applied.*

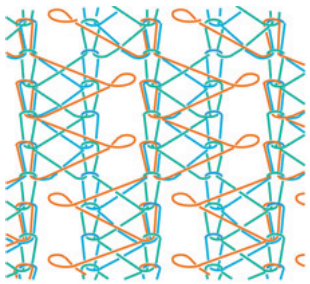
Linear density, dtex	Breaking load, cN	Tenacity, cN/tex	Elongation, %	Shrinkage in % at	
				36 °C	120 °C
46.9 ± 0.5	263.0 ± 1.0	56.0	34.0 ± 0.7	0.09 ± 0.03	1.30 ± 0.13

Table 2. *Parameters of the knitting process and weave schemes of the knitted fabrics elaborated [28].*

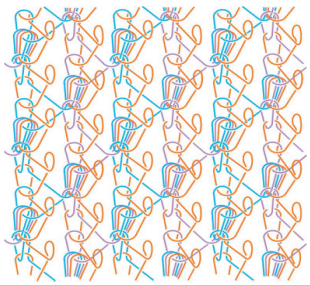
Variant code	Entry links of chains patterning the knitting fabric	Warp feed	Reception of knitted fabrics	Weave schema
Variants of knitted fabrics applicable as 3D gynecological or hernia implants				
SP1-35	Hackle No. 3. 6 7 6 / 4 3 4 / 6 7 6 / 4 3 2 /1 0 1 / 3 4 3 / 1 0 1 / 3 4 5 // Hackle No. 2.4 5 4 / 3 2 3 / 4 5 4 / 3 2 2 /1 0 1 / 2 3 2 / 1 0 1 / 2 3 3 // Hackle No. 1.1 0 1 / 2 3 2 / 1 0 1 / 2 3 3 /4 5 4 / 3 2 3 / 4 5 4 / 3 2 2 //	Hackle No. 1.– 3100 mm/Rack Hackle No. 2.– 3100 mm/Rack Hackle No. 3.– 2200 mm/Rack	Changing circles – A 104; B 56, 11.24 wale/cm	A
SP1-43		Hackle No. 1.– 2400 mm/Rack Hackle No. 2.– 2600 mm/Rack Hackle No. 3.– 2600 mm/Rack	Changing circles – A 108; B 86, 16.62 wale/cm	
SP1-48		Hackle No. 1.– 2400 mm/Rack Hackle No. 2.– 2400 mm/Rack Hackle No. 3.– 2220 mm/Rack	Changing circles – A 93; B 108, 24.24 wale /cm	
SP2-27	Hackle No. 3.1 0 1 / 3 4 3 // Hackle No. 2.2 3 2 / 1 0 1 / 2 3 2 / 2 3 2 // Hackle No. 1.2 3 2 / 2 3 2 / 2 3 2 / 1 0 1 //	Hackle No. 1.– 2320 mm/Rack Hackle No. 2.– 2320 mm/Rack Hackle No. 3.– 4110 mm/Rack	Changing circles – A 108; B 68, 13.14 wale/cm	B
SP2-35		Hackle No. 1.– 2210 mm/Rack Hackle No. 2.– 2210 mm/Rack Hackle No. 3.– 3980 mm/Rack	Changing circles – A 104; B 78, 15.65 wale/cm	
SP3-44	Hackle No. 3.4 5 3 / 1 0 3 / 5 6 3 / 1 0 2 // Hackle No. 2.4 5 3 / 1 0 2 / 4 5 4 / 4 3 4 /4 5 4 / 4 3 4 // Hackle No. 1.1 0 2 / 4 5 3 / 1 0 1 / 1 2 1 /1 0 1 / 1 2 1 //	Hackle No. 1.– 3970 mm/Rack Hackle No. 2.– 3970 mm/Rack Hackle No. 3.– 4920 mm/Rack	Changing circles – A 86; B 41, 9.95 wale/cm	C
SP3-49		Hackle No. 1.– 3500 mm/Rack Hackle No. 2.– 3500 mm/Rack Hackle No. 3.– 5000 mm/Rack	Changing circles – A 104; B 68, 13.65 wale/cm	
DVariant of knitted fabric applicable as a 3D sling for urinary incontinance treatments				
SP5 - sling	Hackle No. 3.1 0 2 / 4 5 4 / 3 2 3 / 4 5 3 /1 0 2 / 2 3 2 // Hackle No. 2.4 3 2 / 2 1 1 / 1 0 1 / 1 2 3 /3 4 4 / 4 5 4 // Hackle No. 1.1 2 1 / 1 0 1 //	Hackle No. 1.– 2730 mm/Rack Hackle No. 2.– 2690 mm/Rack Hacke No. 3.– 3470 mm/Rack	Changing circles – A 104; B 86, 17.26 wale/cm	D

Weave schema

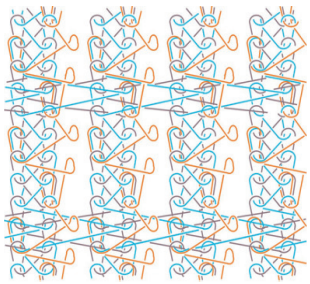
A



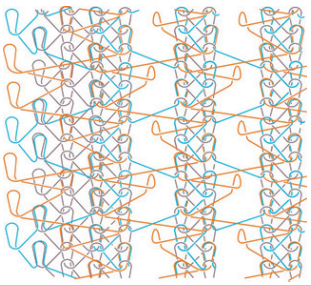
B



C



D



Thickness
The thickness was determined according to Standard PN-EN ISO 5084:1999.

Tensile strength
The tensile strength in the longitudinal or vertical direction was determined according to Standard PN-EN ISO 13934-1:2002.

Elongation at break
The elongation at break in the longitudinal or vertical direction was determined according to Standard PN-EN ISO 13934-1:2002.

Suture pull-out strength
The suture pull-out strength in the longitudinal and vertical directions or in knitting fabric corners was determined according to a modified procedure of ISO 7198:1998 [25].

Bursting strength
The bursting strength was determined using a semi-spherical stamp according to Standard PN-EN ISO 12236:1998 and the procedure described in [ER, ER] which simulates the ideal curvature of the human abdomen. Values of the bursting strength in the relation to the unit of the circumference and replacement at 16 N/cm as well as at the rupture were also calculated.

Bursting pressure by the air-pressure upholster method
The bursting pressure was determined by the air-pressure upholster method, simulating intra-abdominal pressure [26].

3-D knitted variants for urinary incontanancy treatments
Risk analysis was also a useful tool for the selection of analytical methods to estimate the hazards related to clinical complications, both intraoperative and long-term.

The risk analysis for 3-D knitted variants potentially used in hernia or gynecological reconstructions indicates the necessity of verifying the following: the surface weight, thickness, the tensile strength and elongation at break in the longitudinal direction, and the initial elasticity modulus.

Surface mass
The surface mass was determined according to Standard PN-EN 12127:2000.

Thickness
The thickness was determined according to Standard PN-EN ISO 5084:1999.

Tensile strength
The tensile strength in the longitudinal direction was determined according to Standard PN-EN ISO 13934-1:2002.

Elongation at break
The elongation at break in the longitudinal direction was determined according to Standard PN-EN ISO 13934-1:2002.

Initial elasticity modulus
The stiffness modulus in the longitudinal or vertical direction was determined ac-

cording to Standard PN-EN ISO 13934-1:2002, the procedure for which is described in [27].

Results and discussion

Mechanical properties of 3-d knitted variants for hernia treatment or gynecological reconstructions

The most important factors affecting the effectiveness of gynecological or abdominal reconstructions and clinical safety are the following:

a) factors describing the physical behaviour of implants, such as surface mass and thickness;
b) factors describing the mechanical properties of implants, such as tensile strength, elongation at break, bursting strength and bursting pressure.

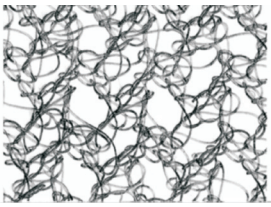
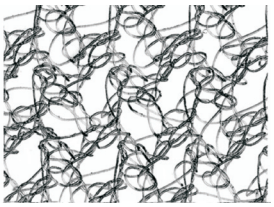
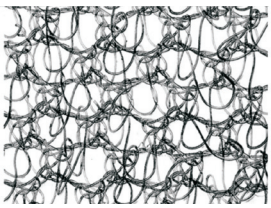
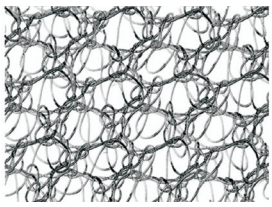
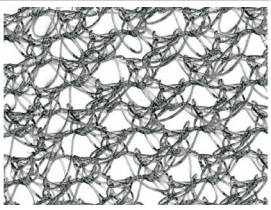
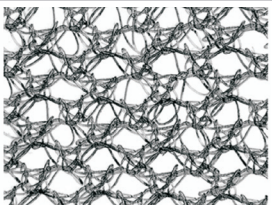
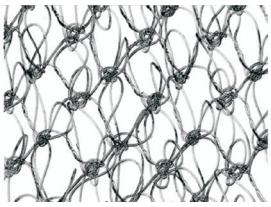
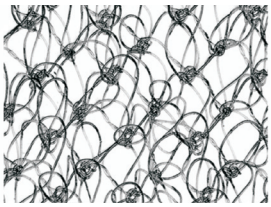
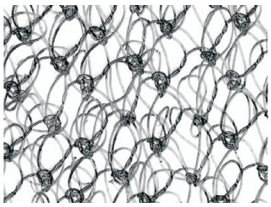
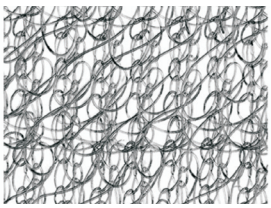
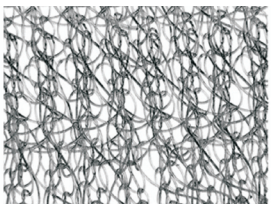
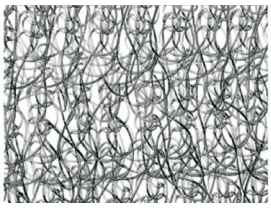
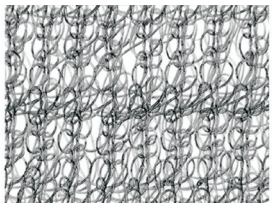
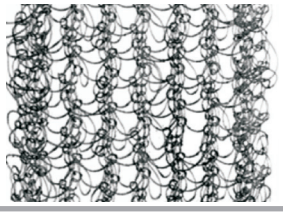
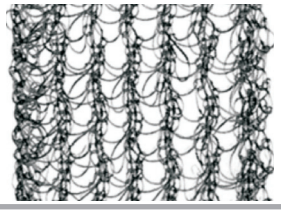
The surface weight and thickness of hernia or gynecological implants are responsible for the quality and quantity of the inflammatory reaction after implantation, both in the short and long term. Reduction in the parameters mentioned above improves the long-term biocompatibility of implants, due to the relatively low surface weight and low thickness which favours a significant reduction in acute and chronic inflammation. A reduction in inflammation is crucial for effective abdominal fascia and vaginal wall reconstructions. A high inflammatory reaction affects massive scar formation, which will stiffen the structures of the abdomen or vagina, causing the significant discomfort of patients or, in drastic cases, a problem with breathing due to the introduction additional pressure onto the diaphragm (i.e. in large reconstructions of the abdominal wall).

Photographs of the 3-D knitted fabrics elaborated, differing in waves and compactness, are shown in ***Table 3***.

Results of the surface weigh, thickness, tensile strength and elongation at break for 3-D variants potentially used in hernia treatment or gynecological reconstructions are shown in ***Figures 1 – 4***.

The lowest thickness is usually co-correlated with a low surface weight of the implant. An optimal value of the surface weight and thickness was shown for all the variants of 3-D knitting fabrics except SP2-35, characterised by a significantly high thickness (1.20 ± 0.05 mm). From a physiological point of view, the thickness

Table 3. *Photographs of elaborated 3-D knitted fabrics.*

Variant code	Flat side	Side with 3-D stitched loops
Variants of knitted fabrics applicable as the 3D gynecological or hernia implants		
SP1-35		
SP1-43		
SP1-48		
SP2-27		
SP2-35		
SP3-44		
SP3-49		
Variant of knitted fabric applicable as the 3D sling for urinary incontinance treatments		
SP5 - sling		

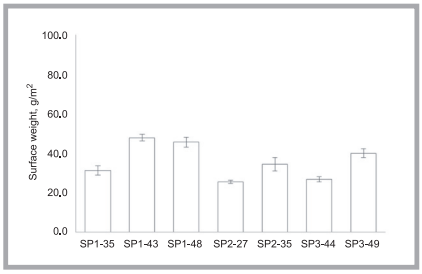


Figure 1. *Surface weight of 3-D variants for hernia treatment or gynecological reconstructions.*

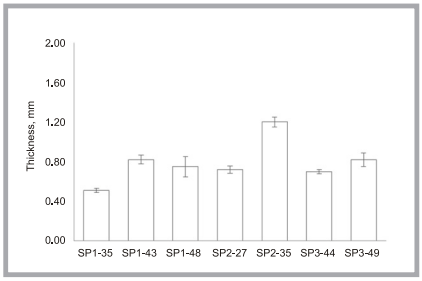


Figure 2. *Thickness of 3-D variants for hernia treatment or gynecological reconstructions.*

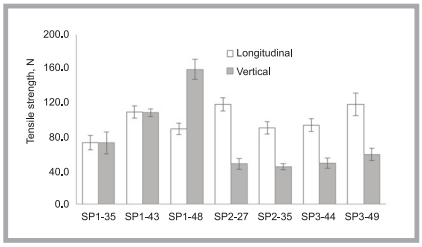


Figure 3. *Longitudinal and vertical tensile strength of 3-D variants for hernia treatment or gynecological reconstructions.*

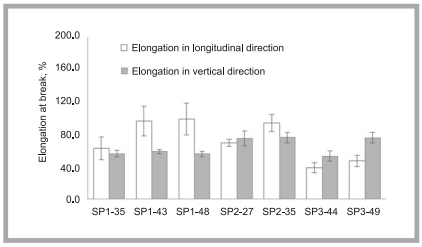


Figure 4. *Longitudinal and vertical elongation at break of 3-D variants for hernia treatment or gynecological reconstructions.*

of connective tissue implants should be as low as possible, in any case less than 1 mm. A similar phenomenon is connected with the surface weight. Standard hernia implants are characterised by a surface weight ranging from 60 to 200 g/m2. A reduction in the surface weight combined with an increase in the surface of the loops ought to favour a reduction in the post-implantation inflammatory reaction. The resistance of implants against elongation forces acting in the abdominal or vaginal walls is important to retain the long-term effectiveness of the surgical reconstructions.

Figure 3 shows the results of tensile strength values determined in the longitudinal or vertical directions for each variant of 3-D implant.

The highest value of tensile strength was obtained for variants SP1-48 and SP1-43. A decrease in surface weight favours a significant reduction in tensile strength, especially in the longitudinal direction.

The proportion of longitudinal and vertical elongation at break values of SP1-43 and SP1-48 are similar to those obtained in ex-vivo studies [6, 23] for abdomen muscles (***Figure 4***).

The suture pull-out strength values of all variants, except SP2, were above the anatomical requirements (***Figure 5***). The lowest suture pull-out strength for SP2 variants was determined, which excludes them as optimal implants for hernia or vagina wall reconstructions due to the potential risk of implant replacement with following clinical complications after the suture place rupture as well as the ineffectiveness of the surgical reconstructions.

Resistance against intra-abdominal pressure is the most important criterion for the selection of appropriate variants of implants, especially in the case of hernia treatments.

Results of the maximal bursting pressure obtained from two different methods: using a semi-spherical stamp or air-pressure, indicated that all the 3-D variants designed met anatomical requirements: the intra-abdominal pressure should not exceed 20 kPa [5, 22-25] (***Figures 6*** and ***8***). Comparison of the results obtained from both methods shows a similar order of magnitude and tendency; the differences that may occur due to various analytical methodologies. However, the calculation of the bursting strength per circumference, as described in [23], indicates only three variants: SP1-43, SP1-48 and SP3-49 which fulfill the anatomical requirements (bursting strength > 16 N/cm) (***Figure 7***). There is no explanation for the phenomenon mentioned above. Moreover, the differences between the anatomical limitations from the literature incline to provide more validated research data from the *post-mortem* or

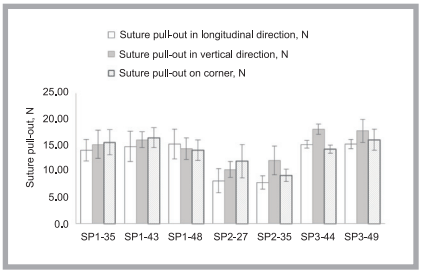


Figure 5. *Longitudinal, vertical or on corner suture pull-out of 3-D variants for hernia treatment or gynecological reconstructions.*

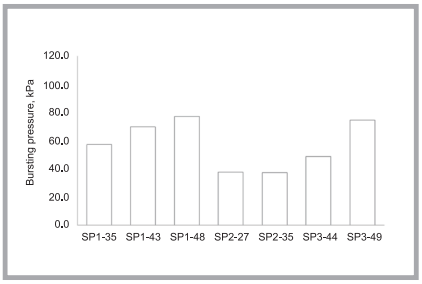


Figure 6. *Bursting pressure of a semi-spherical stamp of the 3-D variants for hernia treatment or gynecological reconstructions.*

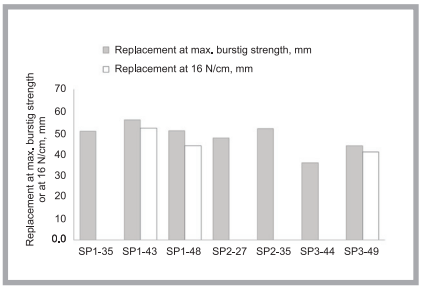


Figure 7. *Replacement at maximal bursting strength and at 16 N/cm of the 3-D variants for hernia treatment or gynecological reconstructions (SP1-35, SP2-27, SP2-35 and SP3-44 variants ruptured below 16 N/cm).*

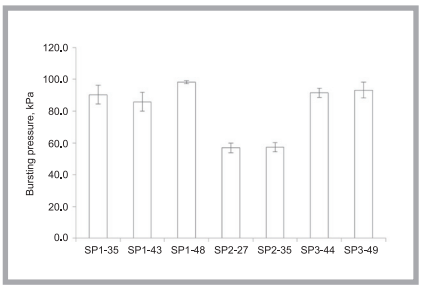


Figure 8. *Bursting pressure at rupture determined by the air-pressure method for 3-D variants for hernia treatment or gynecological reconstructions.*

ex-vivo studies, which will be the aim of planned future studies during the verification of selected 3-D variants on an animal model (acc. Standard ISO 10993-6).

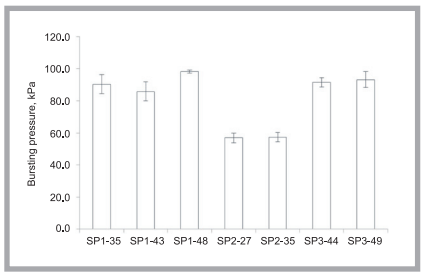


Figure 9. *Relationship between the bursting pressure applied and replacement of 3-D variants for hernia treatment or gynecological reconstructions.*

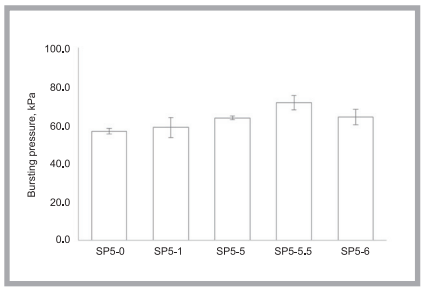


Figure 10.* *Surface weight of 3-D slings for urinary incontinence treatments.*

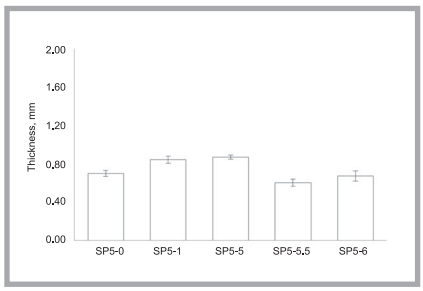


Figure 11. *Thickness of 3-D slings for urinary incontinence treatments.*

As shown in ***Figure 9***, the replacement of the 3-D variants does not exceed 15 mm at a maximal intra-abdominal pressure of 20 kPa.

Mechanical properties of 3-D knitted slings for urinary incontinance treatments

The main factors of the implant which affect the effectiveness of urinary incontinence treatment are the following:

a) factors describing the physical behaviour of implants, such as the surface mass and thickness;
b) factors identifying the mechanical properties of implants, such as the longitudinal tensile strength, longitudinal elongation at break and initial modulus of elasticity.

Results of the physical and mechanical properties of the 3-D knitted slings elaborated are presented in ***Figures 10 – 14***.

A reduction in the temperature of the stabilisation plate favoured a insignificant reduction in the surface weight (***Figure 10***), ranging from approx. 71 g/m^2 (SP5-5.5 variant) to 57 g/m^2 (SP5-0 variant).

The phenomenon of a change in the values of surface weight and thickness (***Figure 11***) is probably connected with the synergistic action of the thermal shrinkage and stiffening of the polypropylene of the 3-D sling during stabilisation, which may vary depending on the temperature of the stabilisation applied as well as on the disappearance of the 3-D structure at a relatively high temperature of stabilisation (at 165 °C), being above the melting point of the polypropylene used (162 °C).

The longitudinal tensile strength of the 3-D slings elaborated ranges from 56 N to 65.5 N, values similar to those of equivalent medical devices clinically used [27].

The tensile strength of the sling variants is insignificantly dependent on the stabilisation temperature, as shown in ***Figure 12***. The maximal tensile strength was obtained for a sling stabilised at 157 °C (SP5-5.5 variant).

A reduction in the elongation at break is strictly correlated with the stiffening of the 3-D sling with an increase in the temperature of stabilisation and with the shrinkage of polypropylene yarns, as shown in ***Figure 13***.

An optimal parameter of the elongation value of approx. 40% was obtained for 3-D variants stabilised at a temperature higher than 155 °C. However, the disappearance of the 3-D structure for SP5-6 leads to the conclusion that the SP5-5.5 sling variant showed optimal parameters in the presence of an optimal 3-D structure of the knitted slings.

The changes in the initial modulus of elasticity were correlated with the values of elongation (***Figure 14***). The highest modulus was obtained for samples of 3-D slings stabilised at a temperature higher than 155 °C.

Conclusions

Risk analysis is a helpful tool for the selection of verification methodology for medical devices, designed in order to improve their performance and clinical safety. As described in [24], the most critical factor for the estimation of acceptable risk levels, apart from chemical characterisation, biocompatibility verification and clinical validation, is the verification of the mechanical properties of 3-D knitted fabric variants designed for potential application in vaginal wall reconstructions and hernia or urinary incontinence treatments.

The studies presented allowed to select a more appropriate design of the medical devices concerned, taking into account the ordered physical behaviour and mechanical properties. Variants SP1-43 and SP1-48 showed the best predisposition to be selected for use in gynecological and general surgical (hernia's procedures) applications due to the low surface weight, thickness, anatomical tensile strength, and elongation as well as an optimal bursting strength reacting to intra-ab-

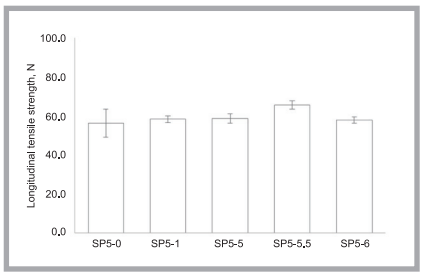


Figure 12. *Longitudinal tensile strength of 3-D slings for urinary incontinence treatments.*

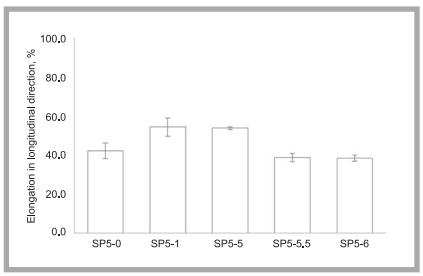


Figure 13. *Longitudinal elongation at break of 3-D slings for urinary incontinence treatments.*

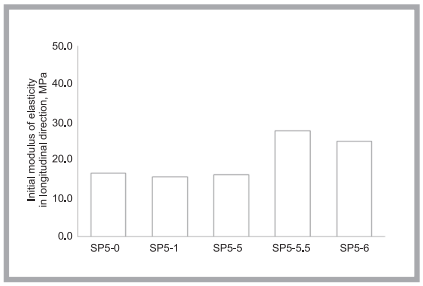


Figure 14. *Initial modulus of elasticity of 3-D slings for urinary incontinence treatments.*

dominal pressure. The mechanical properties of the fabrics elaborated strictly depend on the type of waves and on the compactness of the variants. An increase in the compactness of the knitted fabric variants of implants elaborated for gynecological applications and hernia treatments improves their mechanical properties regardless of the type of wave used.

On the other hand, SP5-5.5 3-D slings, which are equivalent to those clinically used [27], have a comparable longitudinal tensile strength and connective tissue elasticity behavior, but they possess a significantly reduced surface weight and thickness.

The next stage of the research will be an estimation of chemical purity aspects (acc. ISO 10993-18 and ISO/TS 10993-19 standardisation documents), one-side modification of the 3-D variants selected using nano-layers of a more hydrophobic polymer, as well as the verification of designs in *in vitro* and *in vivo* biocompatibility studies (acc. Standard ISO 10993-1).

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