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Biomechanical Studies of Novel Hernia Meshes with Enhanced Surface Behaviour

Abstract

Research on hernia implants, especially less-invasive implantation techniques, is an important focus of study around the world. Practitioners require that these elaborate structures, which are primarily designed using textile technology, possess biomimetic behaviour to significantly reduce post-implantation complications. Novel textile hernia implants are designed with surface modifications that prevent prosthesis migration after implantation. The specialised structural design and enhanced prosthesis surface with stitched loops enables increased surface contact with the fascia, which improves the integration of connective tissue with the prosthesis without overgrowth (thick scar formation). The main intra-operative clinical benefit of the novel implant is its potential utility in suture-less techniques. The aim of this study was to compare novel hernia implant designs to clinically proven, commercially available knitted hernia meshes in vitro. TEMA MOTION 3.5 software was used to analyse motion and estimate the tendency of the non-fixed implants to remain in a stable position at the sublay in a simulated hydrodynamic model of the abdominal wall hernia system. The mechanical resistance of the implant against simulated maximal intra-abdominal pressure, the height of the simulated abdominal wall in the reconstruction region and the curvature of the reconstructions were determined and compared with results obtained with commercial hernia meshes of low surface mass that differ in structure, stiffness and thickness.

Key words: *hernia meshes, knitted textile implants, surface modification, mechanical resistance.*

■ Introduction

Hernia treatments using various surgical techniques (e.g., standard or low-invasive laparoscopic techniques) are important surgical procedures. Leading research around the world is focused on new biomimetic structures. In the USA alone, there are at least 990 000 hernia procedures annually [1 - 5], whereas in Poland, which has a population of 38 million, there are over 60 000 hernia cases annually, and these generally utilise a synthetic non-resorbable or partially resorbable implant.

The present study aims to design an optimal structure for knitted hernia implants. Another goal is to modify these implants with a nano-layer of fluoropolymer and enhance the surface of one side with loops regularly stitched to the plain sur-

face of the implant (resulting in a three-dimensional structure to promote tissue in-growth and prevent uncontrolled migration), as described in our previous publications [6 - 12]. The knitted products are designed with knitwear known to be linear or two-dimensional, as reflected by their parameters (i.e., surface mass). However, the final implants are more complex structures in the direction perpendicular to their length, due to the presence of the stitched loops. Therefore they are designated “three-dimensional” (3-D) to emphasise the clinical importance (clinical performance) of the perpendicular structure of the implant surface [12]. The purpose of the study was to design biomimetic knitted structures that consider the known risks connected with the anatomical location of the implant as well as potential adverse events resulting from clinically used medical devices [10]. One of the research goals was to develop a knitted structure that can be quickly fixed with a low number of or without sutures (suture-less) and that is unlikely to migrate after sublay implantation. To validate the design of the knitted implants in an in vitro environment, hydrodynamic models of an abdominal wall hernia were designed and the behaviour of the implants estimated under simulated abdominal pressure. These implants were compared to commercially

available implants using dynamic motion analysis software.

The hernia mesh variants selected were modified using a low-plasma treatment in the presence of low-molecular mass fluoro-organic derivatives. The effect of these modifications was evaluated using a system to visualise dynamic changes in the implant curvature under simulated intra-abdominal pressure.

Binnebösel, et. al developed a simulation of abdominal pressure action on incisional hernia implants [13]. The model of the abdominal wall hernia designed consisted of a pressure chamber in which a system consisting of an elastic silicone pad (simulating the peritoneal sac), a hernia implant (in the onlay or sublay position) and a silicone pad with bovine muscle. Intrinsic pressure (200 mg Hg) was introduced using a pressure chamber. The hernia was simulated by a flap-like or slit-like cut in the silicone mat.

In [14], a similar standardised model of incisional hernia was used to evaluate the sublay hernia reconstructions that used six types of hernia knitted meshes. The biomechanical behaviour and effectiveness of the fixation (suture-less, point-by-point and fibrin sealant fixation) were estimated.

Table 1. Properties of designed knitted implant variants before and after modification by low-temperature plasma treatment in the presence of tetradecafluorohexane used in the study; ¹⁾ – variant with longer (approx. 2-fold) loops stitched to the plain surface of the implant.

Test method	PN-EN 12127:2000	PN-EN ISO 5084:1999	PN-EN ISO13934-1:2002						PN-EN ISO 12236:2007 using semi-spherical stamp	ISO 7198:1998
			Knitted implant variant	Surface mass, g/m ²	Thickness, mm	Longitudinal tensile strength, N	Vertical tensile strength, N	Longitudinal elongation, %		
Unmodified knitted implant variants										
SP1-35	31.3 ± 2.4	0.51 ± 0.02	72.7 ± 8.5	72.5 ± 13.1	62.6 ± 14.2	56.3 ± 3.8	5.34	6.34	463.0 ± 19.82	15.6 ± 2.4
SP1-43	47.9 ± 1.6	0.82 ± 0.05	109.0 ± 7.2	108.0 ± 4.6	96.5 ± 18.2	58.9 ± 2.8	4.60	4.54	565.0 ± 40.68	16.5 ± 1.9
SP1-48	45.6 ± 2.5	0.75 ± 0.10	88.8 ± 6.8	159.0 ± 11.8	98.6 ± 19.6	55.8 ± 3.2	3.69	7.92	626.0 ± 38.31	14.1 ± 2.0
SP2-27	25.5 ± 0.8	0.72 ± 0.04	118.0 ± 7.7	47.6 ± 6.4	69.7 ± 4.3	75.1 ± 9.1	3.96	1.72	307.0 ± 2.73	12.0 ± 3.2
SP2-35	34.4 ± 3.5	1.20 ± 0.05	90.1 ± 7.0	44.4 ± 3.7	93.7 ± 10.4	75.9 ± 6.4	1.73	1.10	302.0 ± 16.79	9.3 ± 1.2
SP3-44	26.8 ± 1.2	0.70 ± 0.02	93.4 ± 7.4	48.5 ± 6.2	38.8 ± 6.1	53.1 ± 6.3	11.00	2.97	396.0 ± 34.81	14.3 ± 0.8
SP3-49	40.0 ± 2.2	0.82 ± 0.07	118.0 ± 13.2	58.9 ± 7.3	47.2 ± 7.3	75.7 ± 6.4	8.69	2.08	605.0 ± 46.40	16.1 ± 2.0
SP1-48O ¹⁾	45.9 ± 0.8	1.08 ± 0.09 ¹⁾	114 ± 10.1	103.0 ± 8.8	56.1 ± 12.4	72.0 ± 5.2	4.66	2.66	584.0 ± 53.8	20.7 ± 2.6
Implant variant after modification by low-temperature plasma treatment in the presence of tetradecafluorohexane										
SP1-48OM	46.1 ± 1.5	1.1 ± 0.01 ¹⁾	89.0 ± 23.7	110.0 ± 12.8	76.4 ± 8.6	62.7 ± 8.7	0.96	2.4	564.0 ± 26.1	21.7 ± 3.8

Table 2. Properties of reference hernia knitted meshes (commercially available) used in the study.

Test method	PN-EN 12127:2000	PN-EN ISO 5084:1999	PN-EN ISO 13934-1:2002					
			Knitted implant	Surface mass, g/m ²	Thickness, mm	Longitudinal tensile strength, N	Vertical tensile strength, N	Longitudinal elongation, %
DALLOP® PP JS	82.2 ± 3.2	0.46 ± 0.02	230.0 ± 20.1	240.0 ± 3.5	77.0 ± 2.1	78.0 ± 3.9	17.4	18.2
DALLOP® PP TDM	70.6 ± 1.9	0.45 ± 0.02	390.0 ± 26.5	200.0 ± 11.3	63.0 ± 6.3	133.0 ± 10.8	26.8	3.54
OPTOMESH® ThinLight	66.9 ± 0.8	0.38 ± 0.01	330.0 ± 51.8	170.0 ± 11.2	59.0 ± 7.0	139.0 ± 10.5	55.8	20.3

Materials and methods

Materials

Designed knitted implants

Variants of knitted medical devices (SP1 – SP3) were designed using monofilament with a diameter of 0.08 mm (linear density of 46 dtex) made of polypropylene (VIth class polymer acc. US Pharmacopeia). The properties of monofilament yarn and the method of knitted implant fabrication are described in [10]. The knitted implants fabricated differed in structure and surface mass (in range from 30 – 50 g/m²) as described in [10, 12].

The characteristic feature of the novel implants is the inclusion of loops, which range in length from 2 – 4 mm, stitched on one side of the implant. The opposite side of the selected mesh (SP1-48OM) was modified by low-temperature plasma treatments in the presence of organic derivatives with low molecular mass, including tetradecafluorohexane [9]. Physical and mechanical properties of the variants of the knitted implants are presented in **Table 1**. **Table 1** lists the properties of selected variant SP1-48O, a knitted hernia mesh modified by low-temperature plasma treatment.

Reference samples

The following commercially available hernia meshes were used as reference samples:

- DALLOP® PP JS – stiff, knitted hernia mesh made on TRICOMED SA, Poland using multifilament polypropylene yarns;
- DALLOP® PP TDM – soft, highly elastic, knitted hernia mesh made on TRICOMED SA, Poland using multifilament polypropylene yarns;
- OPTOMESH® ThinLight – stiff, knitted hernia mesh made on TRICOMED SA, Poland using polypropylene monofilament with a diameter of 0.16 mm.

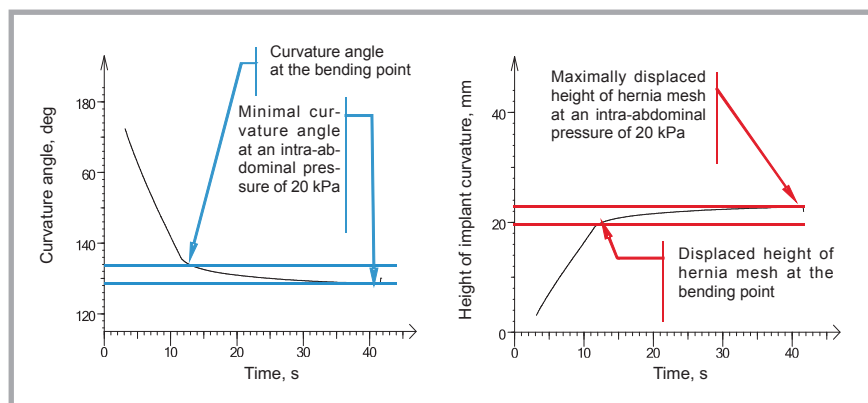


Figure 1. Method used to estimate the height and curvature angle at the bending point of the hernia meshes tested and the maximal displaced height at the minimal curvature angle.

Physical and mechanical properties of the reference hernia meshes are presented in **Table 1**.

Metrological studies were performed under validated conditions at the accredited Metrological Laboratory of the Institute of Biopolymers and Chemical Fibres (Lodz, Poland).

Methods

A multidirectional, hydrodynamic behaviour test of the hernia implants designed was carried out using a specially

constructed simulation of an abdominal wall hernia consisting of a Hydrotester III FX 3000 (Schwerzenbach, Switzerland) and a NIKON HD Everio camera (Japan) (located at the level of the abdominal wall hernia system simulated). TEMA 3.5 Motion analysis software was used to record an image of the behaviour of the abdominal wall anatomical structures simulated (under dynamic changes in intra-abdominal pressure simulated, up to 20 kPa).

The effect of the dynamic change in the intra-abdominal pressure simulated (increase ratio: 100 kPa/min; final simulated intra-abdominal pressure of 20 kPa for approx. 30 s to test the stability of the displaced implant form) on the curvature of the hernia meshes tested was determined. The conditions of the test were selected by considering the most critical conditions (worst case) that may occur during implantation. For each case, the change in curvature angle of the implants and height of the displaced structures, which were affected by the changes in the simulated intra-abdominal pressure, were determined. Results describing the behaviour of the hernia meshes tested consisted of the height and curvature angle at the bending point (the magnitude of pressure at which the structure of the fabric is less deformable) and the maximal displaced height of the hernia mesh at the minimal curvature angle, as shown in **Figure 1**. Three commercially available knitted hernia meshes which differ in properties (surface masses from 65 - 80 g/m²) and structure were studied to validate the system. The fascia was simulated with MVQ/VMQ silicone elastomer sheets (Mikroguma, Poland) with a thickness of 3.8 ± 0.2 mm and a suitable simulation of the flap-like gate of the hernia was performed (the worst case). The knitted implants tested (80 × 80 mm) were localised at the sublay position, as shown in **Figure 2**.

Results and discussion

The results of studies [2, 15 - 17] demonstrated that the intra-abdominal pressure does not exceed approx. 20 kPa under typical anatomical conditions. Moreover the intra-abdominal pressure was 7.9 kPa during a cough or with pressing, 5.9 kPa during pain, 1.7 kPa in the standing position, 1.3 kPa during limited blood flow and 0.8 kPa when lying on the back [2, 15 - 17]. Thus the criterion for simulated

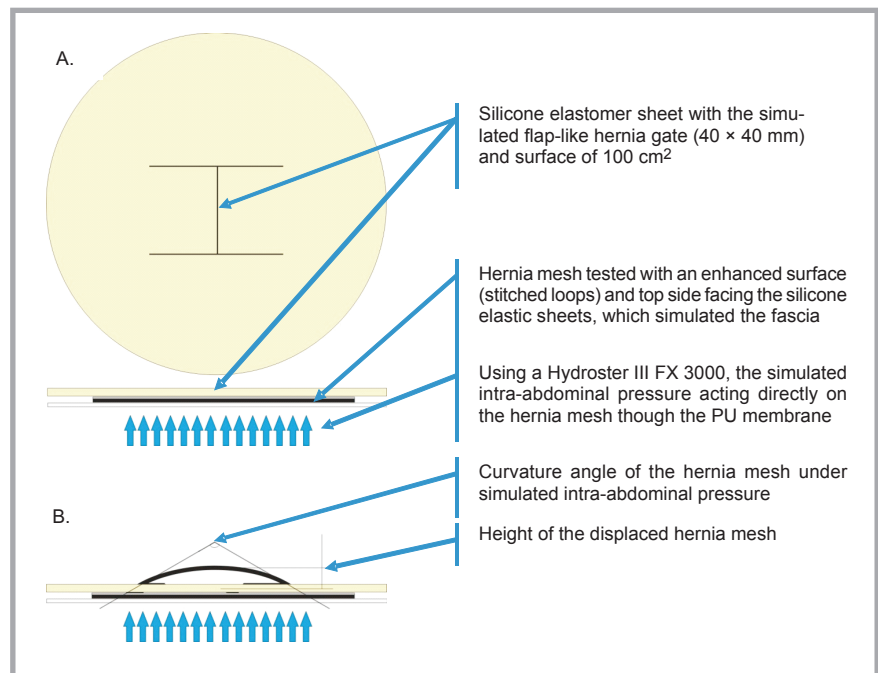
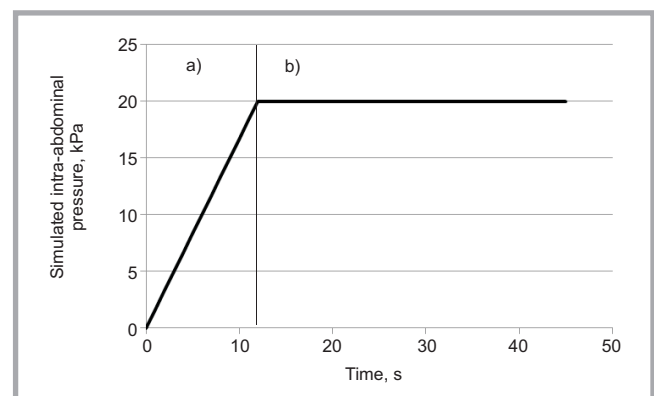


Figure 2. Schema of the multidirectional dynamic system, which simulated the abdominal hernia wall sublay reconstruction: A. visualisation of the flap-like hernia in the silicone elastomer sheet and general action of the system; B. definition of the parameters measured during the study.

Figure 3. Experimental conditions: a) stage I: increase in simulated intra-abdominal pressure at a rate of 100 kPa/min; b) stage II: continuous intra-abdominal pressure of 20 kPa on hernia mesh tested for approx. 30 s.



intra-abdominal pressure was 20 kPa. However, the duration of pressure application on the hernia mesh tested was prolonged, as shown in **Figure 3**, to simulate the worst-case scenario.

The first stage of research determined the effect of the simulated intra-abdominal pressure on the sublay-positioned commercial hernia meshes, which had already been used in the clinic. **Table 3** shows the height and curvature angle at the bending point of the hernia meshes tested as well as the maximal displaced height at the minimal curvature angle. **Figure 5** presents the relationship of the curvature angle of the mesh to its displaced time-on-time using TEMA MOTION 3.5 software.

The results obtained for the clinically proven knitted hernia meshes strongly varied based on their physical properties. The stiff hernia meshes (DALLOP® PP JS) are characterised by a low height (17 mm) under simulated intra-abdominal pressure and a significantly high curvature angle at the bending point (approx. 152°). In the cross-sectional view, the implant did not completely adhere to the simulated abdominal wall, behaving similar to the flat form.

The above results correlate with the low adaptation of the implant curvature to the anatomical shape of the abdomen. In one case, a stiff hernia mesh, OPTOMESH®, which had a surface mass that was approx. 16 g/m² lower, was partially displaced during the test (**Figure 4**). The above results suggest that use in suture-

Table 3. Hydrodynamic test results using the abdominal wall hernia sublay simulated and suture-less reconstruction with commercially available knitted hernia meshes.

Knitted implant variant	Minimal curvature angle, deg	Curvature angle at the bending point, deg	Maximal displacement height, mm	Displacement height at the bending point, mm
DALLOP® PP JS	139.2	151.7	17	12
DALLOP® PP TDM	128.0	136.0	23	19
OPTOMESH®ThinLight	127.8	142.0	23	17

Table 4. Hydrodynamic test results using the abdominal wall hernia sublay simulated and suture-less reconstruction on novel knitted hernia meshes made of polypropylene monofilament.

Knitted implant variant	Minimal curvature angle, deg	Curvature angle at the bending point, deg	Maximal displacement height, mm	Displacement height at the bending point, mm
SP1-35	128.5	134.8	23	20
SP1-43	127.5	134.9	22	19
SP1-48	125.6	133.9	24	20
SP2-27	127.3	134.1	24	20
SP2-35	134.2	138.5	20	18
SP3-44	130.6	135.0	22	20
SP3-49	127.4	135.6	23	19
SP1-48O	143.9	147.6	15	14

Table 5. Hydrodynamic test results using the abdominal wall hernia sublay simulated and suture-less reconstruction on the designed knitted hernia mesh made of the polypropylene monofilament with one-side modified by low-temperature plasma treatment with a fluoroorganic derivative.

Knitted implant variant	Minimal curvature angle, deg	Curvature angle at the bending point, deg	Maximal displacement height, mm	Displacement height at the bending point, mm
SP1-48O	141.2	144.9	16	15

less reconstructions is risky. The primary limitation for successful hernia reconstructions was imprecise positioning of the mesh at all edges of the simulated hernia. Soft, elastic hernia meshes, such as DALLOP® PP TDM, are characterised by good adaption behaviour, as shown by a relatively low curvature angle at the bending point of 136° and a high displaced height (23 mm). This behaviour results from the high elasticity, which is represented by the relatively low modulus of vertical elasticity of 3.54 MPa (*Table 1*).

The next step of the research was to estimate the effect of simulated pressure on the novel hernia meshes. The results are listed in *Table 4*, and the relationships between the curvature angle and displaced

time with the test time, as analysed with TEMA MOTION 3.5 software, are shown in *Figures 6.a, 6.b* and *6.c*.

The maximal displaced height detected for the knitted hernia meshes designed ranged from 15 mm (SP1-48O) to 24 mm (SP2-27), which is comparable to that of clinically used hernia meshes, except the DALLOP® PP JS mesh, which displayed low adaptation to the curvature of the simulated abdomen. Enhancing the surface of the novel hernia meshes with loops stitched to the plain surface of the implant caused, especially in the SP1-48O variant with longer loops, a reduction in the displaced height with a simultaneous higher curvature angle. This phenomenon indicates the perfect adap-

tation of the mesh to the structures of the abdomen simulated and the necessary absence of migration through the hernia gate. The SP1-48O variant displayed high resistance to the intra-abdominal pressure simulated.

Uncontrolled migration was not observed with any variants of the newly designed hernia meshes because of the manufacture of additional loops stitched onto the implant surface, which improved surface contact with the simulated fascia. Moreover the highest values for the curvature angle were detected with the SP1-48O, SP2 or SP3 variants (*Figures 6.b* and *6.c*).

In actual clinical conditions, hernia implants are usually placed near or between anatomical structures of the abdomen (such as *fascia, omentum*, etc.), which additionally stabilises its position. A critical situation occurs when the design of the implant and/or its physical properties, i.e., stiffness, result in the absence of adaptation or low adaptation of the implant's total surface to the surrounding tissue. Low adaptation facilitates the displacement of the hernia mesh, resulting in uncontrolled migration and eventually hernia recurrence.

Table 5 shows the results of simulations of the modified variants of SP1-48O using a low-temperature plasma treatment of the surface opposite the side with stitched loops. *Figure 7* shows the changes in the curvature angle and the displaced height during the increase in the intra-abdominal pressure simulated, as analysed by TEMA MOTION 3.5 software for SP1-48OM variant.

Low-temperature plasma treatment in the presence of tetradecafluorohexane did not significantly affect the features of the knitted implants tested regarding susceptibility to the changes in the intra-abdominal pressure simulated. The curvature angle bending point was insignificantly reduced from 147.2° (SP1-48O – modified variant) to 144.9° (SP1-48OM initial, unmodified variant), and the displaced height increased by approximately 1 mm (14 mm for the SP1-48O variant; 15 mm for the SP1-48OM modified variant). An insignificant reduction in the stiffness of the modified variant of the knitted implant (initial modulus of the longitudinal elasticity; *Table 1* confirms its behaviour during the simulation.

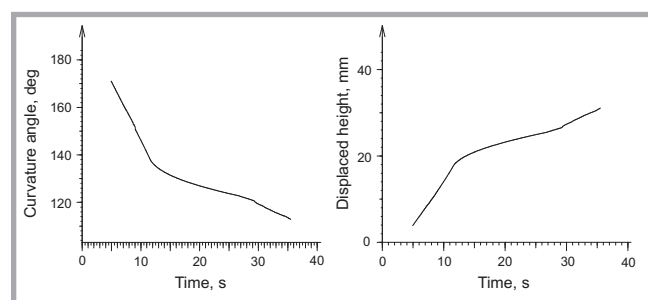


Figure 4. Results of the hydrodynamic test using the abdominal wall hernia sublay simulated and suture-less reconstruction for the Optomesh® during prosthesis migration.

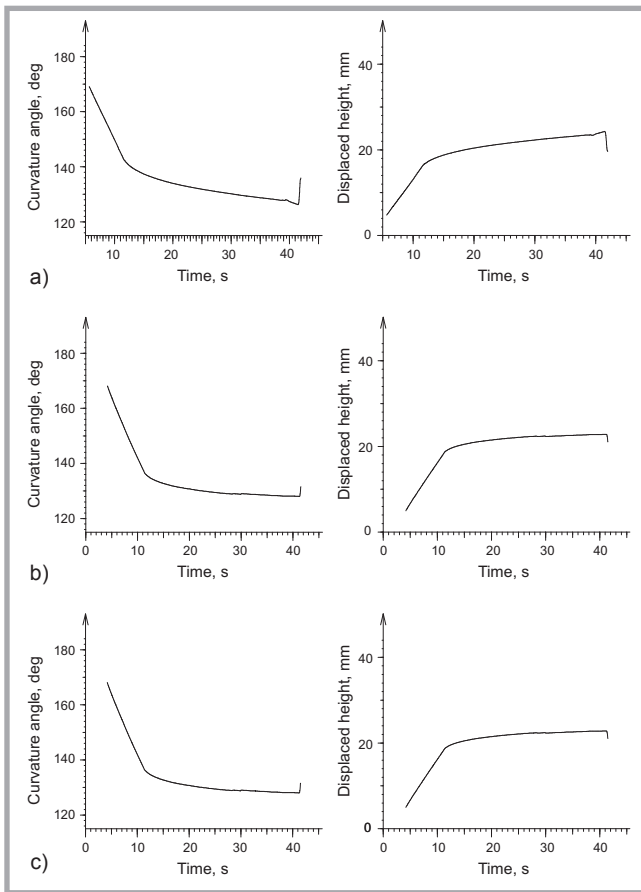


Figure 5. Results of the hydrodynamic test using the abdominal wall hernia sublay simulated and suture-less reconstruction for the commercially available knitted hernia meshes: a) Optomesh®ThinLight; b) Dallop® PP JS; c) Dallop® PP TDM.

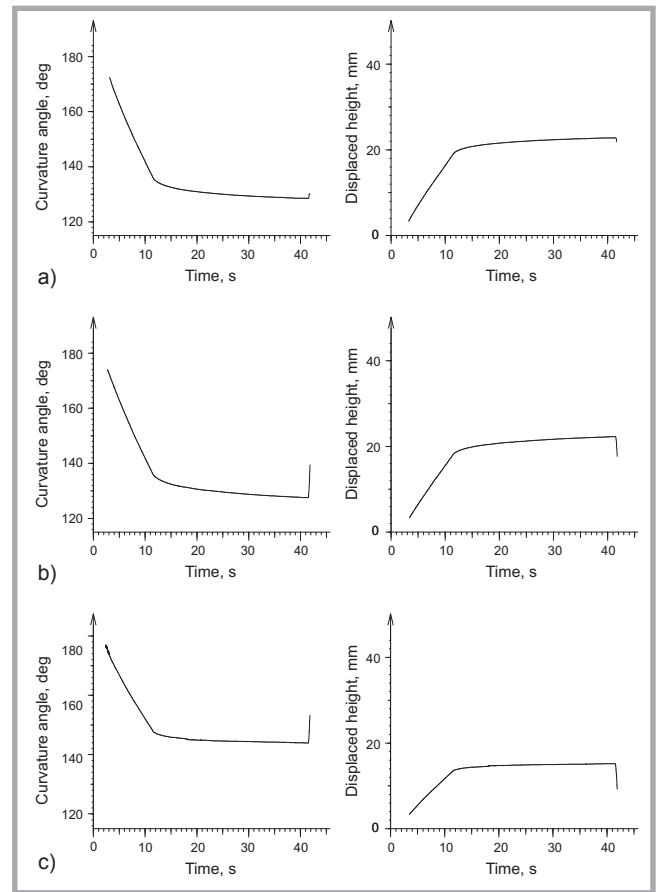


Figure 6.a. Results of the hydrodynamic test using the abdominal wall hernia sublay simulated and suture-less reconstruction for the designed variants of knitted hernia meshes made of polypropylene monofilament: a) SP1-35; b) SP1-43; c) SP1-48.

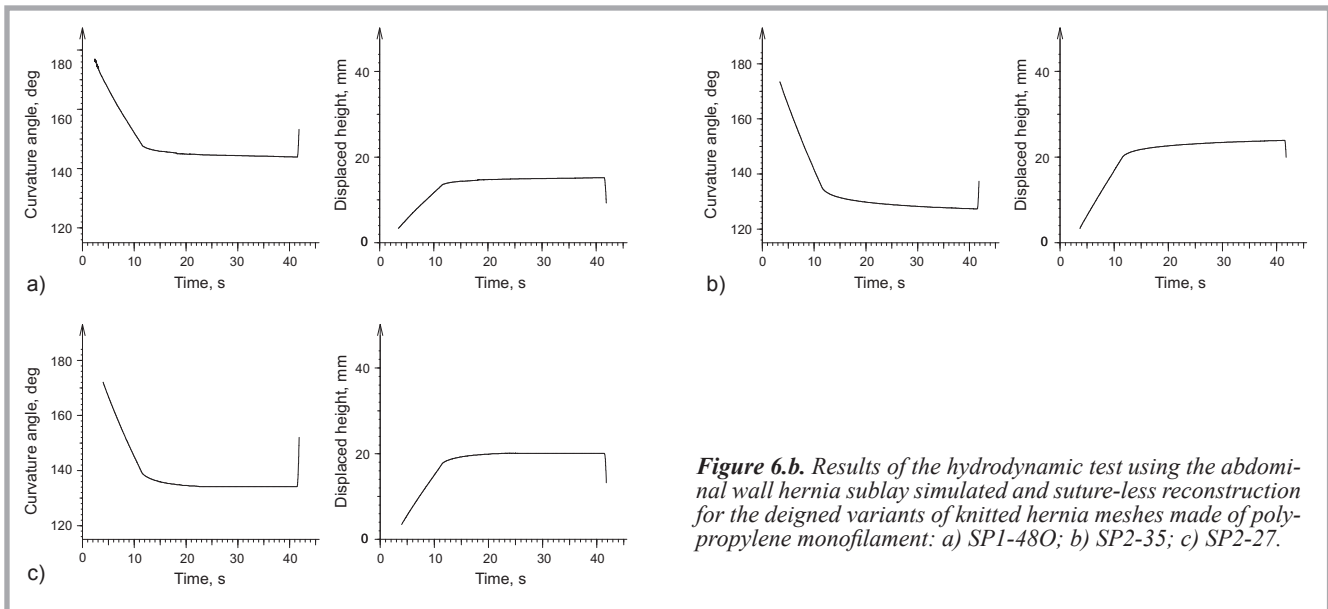


Figure 6.b. Results of the hydrodynamic test using the abdominal wall hernia sublay simulated and suture-less reconstruction for the designed variants of knitted hernia meshes made of polypropylene monofilament: a) SP1-48O; b) SP2-35; c) SP2-27.

Conclusions

The systems designed simulated hydrodynamic hernia abdominal wall behaviour after reconstruction of hernia implants. This enabled modification of the novel implants to reduce the poten-

tial risk of implant migration and hernia recurrence, especially with suture-less fixation.

Preliminary risk estimation in preclinical tests by selecting optimal variants is important for designing new implants.

This research assessed the susceptibility of implant deformation caused by simulated intra-abdominal pressure, the adaptation of the structures of the abdominal wall simulated, the tendency of the implant to migrate uncontrollably through the simu-

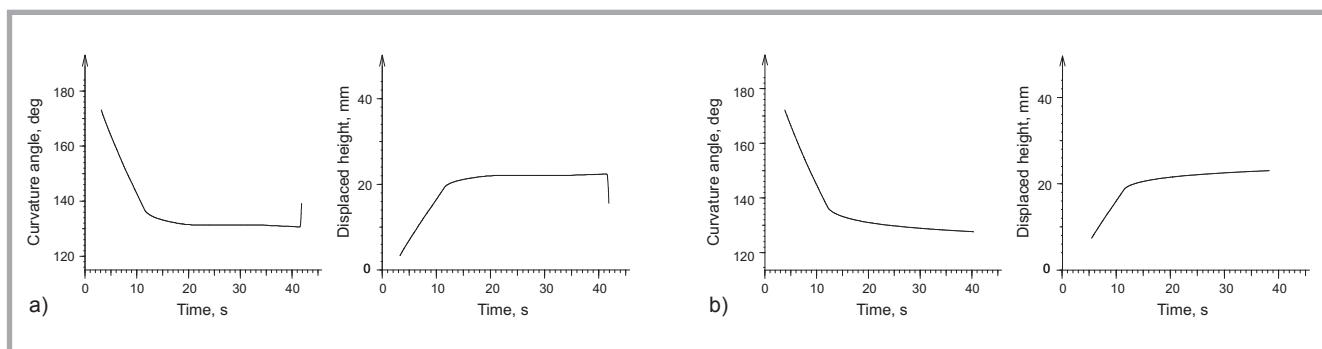


Figure 6.c. Results of the hydrodynamic test using the abdominal wall hernia sublay simulated and suture-less reconstruction using the designed variants of knitted hernia meshes made of polypropylene monofilament: a) SP3-44; b) SP3-49.

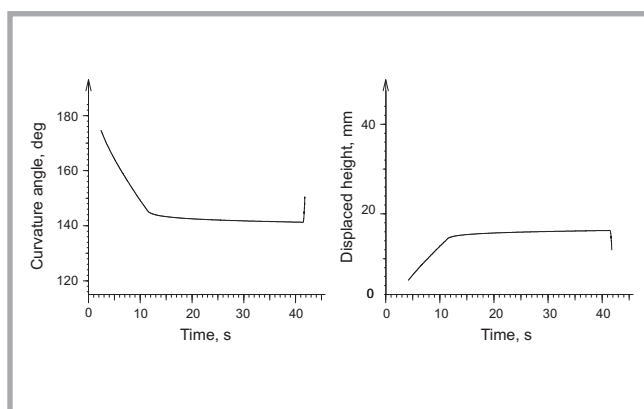


Figure 7. Results of the hydrodynamic test using the abdominal wall hernia sublay simulated and suture-less reconstruction for the designed SP1-48OM knitted hernia mesh made of polypropylene monofilament and modified on one side by low-temperature plasma treatment with a fluoroorganic derivative.

lated hernia gate, and the effect of intra-abdominal pressure on the behaviour of the implants.

The novel variants of knitted hernia mesh better adapted to the curvature of the abdomen simulated than clinically used hernia implants, with differing physical properties. These changes in shape adaptation were a result of the structures of knitted implants as well as their mechanical properties, evaluated using TEMA MOTION 3.5 software. Moreover, insignificant changes were observed between the adaptation variants treated by low-plasma in the presence of the fluoroorganic derivatives and the unmodified mesh in response to dynamic intra-abdominal pressure.

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