

Marcin H. Struszczyk,  
Agnieszka Gutowska<sup>1</sup>,  
Beata Pałys<sup>1</sup>,  
Magdalena Cichecka<sup>2</sup>,  
Krzysztof Kostanek,  
Bożena Wilbik-Hałgas<sup>2</sup>,  
Krzysztof Kowalski<sup>3</sup>,  
Kazimierz Kopias<sup>3</sup>,  
Izabella Krucińska

Department of Commodity,  
Material Sciences and Textile Metrology,  
Faculty of Material Technologies  
and Textile Design,  
Lodz University of Technology,  
ul. Żeromskiego 116, 90-924 Łódź, Poland  
E-mail: marcin.struszczyk@hotmail.com

<sup>1</sup> Institute of Biopolymer and Chemical Fibres,  
ul. Skłodowskiej-Curie 19/27, 90-570 Łódź, Poland

<sup>2</sup> Institute of Security Technologies "MORATEX",  
ul. Skłodowskiej-Curie 3, 90-965 Łódź, Poland

<sup>3</sup> Knitted Department,  
Faculty of Material Technologies  
and Textile Design,  
Lodz University of Technology,  
ul. Żeromskiego 116, 90-924 Łódź, Poland

## ■ Introduction

The wide range of clinically available solutions for textile medical devices applicable in general surgery as well as urogynaecological reconstruction allows the improvement of surgical procedures. However, the presence of a so-called "foreign body" causes several adverse effects. Taking the above into account, continuous research is carried out to design more biocompatible implants mostly connected to the reduction of surface mass (while maintaining anatomical strength) and modification of the surface of implants to control the in-growth of connective tissue [1 - 6].

Currently, in Poland, standard knitted implants for open or laparoscopic hernioplasty techniques are manufactured. Their main sources are non-resorbable polyester and polypropylene (both monofilament and multifilament). The mechanical strength ( $>> 100$  N) and surface mass ( $> 60$  g/m<sup>2</sup>) are significantly higher than required anatomically classifying the above-mentioned medical devices as light or heavy implants [7], resulting in low biomimetic behaviour.

A new type of knitted implant for laparoscopic hernioplasty (IPOM technique)

# Accelerated Ageing of the Implantable, Ultra-Light, Knitted Medical Devices Modified by Low-Temperature Plasma Treatment – Part 1. Effects on the Physical Behaviour

## Abstract

*The aim of the research was to validate the effects of accelerated ageing on the physical properties of newly-designed ultra-light three dimensional (3-D) knitted implants undergoing one-sided modification by low-temperature plasma treatment using low molecular weight fluoroorganic donors. The influence of storing the knitted medical devices for 1 or 2 years at accelerated conditions was studied taking into account their selected physical properties in relation to key usable features. The presented study is a continuation of previous research for the elaboration of a new-idea of three-dimensional implants applied in hernioplasty (general surgery), vaginoplasty and urinary incontinence treatment (urology-naecology).*

**Key words:** implants, ultra-light medical devices, knitted structures modification, low-temperature plasma, physical behaviour.

was clinically implemented. It consisted of 90 wt% of polyvinylidene fluoride (PVDF) monofilament and 10% of polypropylene monofilament. A small amount of polypropylene is necessary to induce an inflammatory response, supporting the rapid stabilisation of the prosthesis by in-growing tissue. The proposed implants show significantly higher surface mass ( $>> 120$  g/m<sup>2</sup>) effecting the loss of biomimetic behaviour and the negative performance of patient's comfort. Additionally, statistical arrangement of the PVDF yarns yielded in the significant reduction of assumed performance.

The stability of the usable properties of medical devices during the storing is a crucial feature describing their safety during standard clinical usage. The loss of the required properties of medical devices affects the new risks related to, in limited situations, the total incapability of the product. The chemical impurities, uncontrolled degradation, loss of sterility as well as the significant changes in the physical behaviour of medical devices during storage are the main hazards that need to be assessed for their acceptance before implementation. In addition, the new knowledge resources about the behaviour of the new materials and the final products overall provides an explanation of the phenomena of instability or stability of the new features of the designed medical devices and improves the future design processes. The changes in properties of the medical devices during the storage should be linked with the accept-

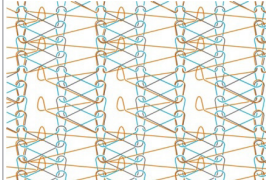
ance levels resulting from the established clinical applications. The recognition of alterations in the macro- and microstructures takes place during the storage of medical devices, as well as the identification of the causes of the changes allowing the process of product design applied in medicine to be optimised.

In the literature there is an absence of publications describing the verification of the time-stability of the elaborated performance of the designed medical devices. The essential requirements covered by the European Directives 93/42/EEC and 2007/47/EC demand the confirmation of stability of the assumed key features of medical devices after storing for a time defined by the manufacturer, and the most critical aspects of safety and performance validation. Moreover, the rationality points to the necessity of time-stability verification of key features of newly-designed medical devices.

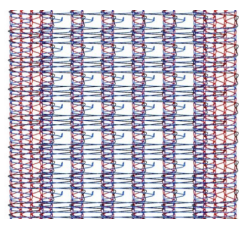
There are no standardised requirements that indicate the appropriate way to study the newly-designed medical devices. ASTM 1980 F Standard [8] defines only the guide for the accelerated studies of packaging used for medical devices based on two factors: temperature and humidity, as an idea of the zero, first or pseudo-first-order degradation reactions described by the Arrhenius' equation according to previous studies [8, 9].

The above-mentioned guidelines were adopted during this research for the estimation of alterations in physical and

**Table 1.** Parameters of knitting process and weave schemes of elaborated knitted fabrics for a gynaecological or hernia implant.

| The entry links of chains patterning knitting fabric   | Warp feed  | Reception of knitted fabrics                       | Weave scheme  |
|--|--|--|---|
| Hackle No. 3. 8 9 7 / 6 5 6 /<br>8 9 7 / 6 5 3 / 1 0 3 / 5 6 2 /<br>1 0 3 / 5 6 7 //<br>Hackle No. 2. 4 5 4 / 3 2 3 /<br>4 5 4 / 3 2 2 / 1 0 1 / 2 3 2 /<br>1 0 1 / 2 3 3 //<br>Hackle No. 1. 1 0 1 / 2 3 2 /<br>1 0 1 / 2 3 3 / 4 5 4 / 3 2 3 /<br>4 5 3 / 3 2 2 // | Hackle No. 1<br>– 2600 mm/Rack<br>Hackle No. 2<br>– 2600 mm/Rack<br>Hackle No. 3<br>– 4800 mm/Rack | Changing circles<br>– A 108; B 86<br>16,62 wale/cm |  |

**Table 2.** Parameters of knitting process and weave schemes of elaborated knitted tape for an implant used for urinary incontinence treatment.

| The entry links of chains patterning knitting fabric  | Warp feed  | Reception of knitted fabrics                       | Weave scheme  |
|---|--|--|---|
| Hackle No. 3. 1 0 2 / 4 5 3 /<br>1 0 2 / 4 5 3 / 3 2 3 / 4 5 3 //<br>Hackle No. 2. 1 2 2 / 1 0<br>0 //<br>Hackle No. 1. 5 5 3 / 2 1 3 /<br>5 5 1 / 0 0 0 / 0 1 1 / 0 0 2 // | Hackle No. 3 –<br>7000 mm/Rack<br>Hackle No. 2 –<br>3200 mm/Rack<br>Hackle No. 1 –<br>5000 mm/Rack | Changing circles<br>– A 104; B 56<br>11,28 wale/cm |  |

chemical properties, as well as the stability of acquired surface modifications of newly-designed medical devices: knitted three-dimensional implants for hernioplasty and vaginoplasty as well as knitted three-dimensional tape for women with urinary incontinence.

However, some detailed explanations considering the three-dimensional idea of the final implants' design should be given. The designed knitted products, in the form of tapes or sheets, are defined on the basis of the knitwear knowledge, as linear or two-dimensional products, mirrored by their parameters, such as linear (tape) or surface mass (sheet). On the other hand, the designed implants show more complex structures in a direction perpendicular to their length (in the form of loops stitched to a plain surface of the implant promoting tissue in-growth, as well as preventing its uncontrolled migration). Therefore, the designation of the structure as “three-dimensional (3-D)” in order to emphasise the clinical importance (clinical performance) of the perpendicular enhancement of the implant surface seems to be justified.

The presented study is a continuation of a previous research for the elaboration of the new-idea of three-dimensional implants applied in hernioplasty (general surgery), vaginoplasty and urinary incontinence treatment (urogynaecology). The idea of knitted implants is to design

three-dimensional knitted structures for quicker connective tissue in-growth by irregular loops stitched to one surface of the implant and modification by low temperature plasma onto the opposite side to avoid the visceral adhesions formed by fistula formation.

The part of this research was carried out for the evaluation of the stability of designed knitted implants following surface modification by low temperature plasma after accelerated ageing [13]. The proper evaluation of the effects of ageing on the elaborated knitted implants also needs the consideration of other features, such as influence on the physical properties as well as chemical leakage profile.

It was assumed that the designed knitted implants will remain the key features during the accelerated ageing, thus the research programme for testing was elaborated on the basis of the risk analysis.

The design process of the above-mentioned implants and the verification of key features were described previously [10 - 15], as the inputs for this research that validate the stability of the physical properties of the designed knitted implants during accelerated ageing.

The physical properties of newly-designed medical devices were assigned on the basis of risk analysis performed

according to Standard PN-EN ISO 14971:2009, as described in [16].

## Materials and methods

### Materials

#### Raw-materials

Knitted medical devices for hernioplasty and vaginoplasty, as well as for urinary incontinence treatment, were designed using monofilaments with a diameter of 0.08 mm (linear density of 46 dtex) made of polypropylene; these were of a quality approved for implantation (the VI<sup>th</sup> class polymer acc. US Pharmacopeia). The properties of monofilament yarn are described in [11].

#### Design of implantable medical devices

The design of knitted medical devices for hernioplasty, vaginoplasty and urinary incontinence treatment was optimised in the Department of Knitting Technology of the Lodz University of Technology based on the outputs of earlier experiments [11,15].

The parameters of the knitted process for all of the elaborated variants of knitted implants are shown in **Tables 1 & 2**.

#### Low temperature plasma surface modification of designed implantable medical devices

One-sided modification of knitted implants was performed in the Department of Commodity, Material Sciences and Textile Metrology of the Lodz University of Technology using low temperature plasma treatment with fluorine organic derivatives (tetradecafluorohexane/Fluka) using CD 400PLC ROLL CASSETTE Plasma system, as described in [12].

The main modification process using a fluoroorganic compound was carried out for 10 min.

#### Finishing of implantable medical devices

Knitted implants, modified by low-temperature plasma treatment with tetradecafluorohexane, underwent ultrasound purification to remove physical contamination, free-reagents and low molecular weight results of plasma modifications according to [12].

Then, elaborated prototypes of knitted implants were shaped, packed in clean-room conditions (class D) into the appropriate medical packaging system (OPM/Poland) and steam-sterilized at 121 °C

for 30 min. at the TZMO SA sterilisation plant/Lodz.

### Packaging system

The prototypes of knitted implants were packed in the double medical grade packaging system, which is adaptable for steam sterilisation (OPM/Poland). The size and form of the packaging system were adequate for the knitted implants.

### Accelerated ageing

Accelerated ageing of knitted implantable medical devices was carried out according to the adopted guide of the ASTM F 1980:2002 Standard in an accredited Metrological Laboratory of the Institute of Security Technologies "MORATEX".

The process of accelerated ageing of designed knitted implants was carried out using the TK 720 ageing chamber (BINDER GmbH) with the temperature rise as an accelerated ageing factor.

Two periods of storage of designed implants were performed:

- 1 year of real-time storage being, equivalent to 28 days at simulation (I stage) and
- 2 years of real-time storage, being equivalent to 56 days at simulation (II stage) [8].

The acceleration ageing periods were calculated based on the following equations:

$$t_{T1} = \frac{t_{RT}}{Q_{10}^{\frac{T1 - TR}{10}}} \quad [8],$$

where:

- $t_{T1}$  – accelerated ageing period;
- $t_{RT}$  – time of the storing at the ambient temperature;
- $T_{T1}$  – temperature of the accelerated ageing (60 °C);
- $T_{RT}$  – ambient temperature (23 °C);
- $Q_{10}$  – ageing factor (10).

The sterile prototypes of knitted implants, packaged in the described packaging systems, were introduced into the ageing chamber and the temperature of  $60 \pm 2$  °C was maintained during stages I and II of the study. The choice of the temperature level was limited by two criteria: (1) risk of the possible thermal degradation of the polymers at higher than 60 °C for the implants, as well as packaging systems used, and (2) the use of the highest possible temperature being the critical worst case of the study. The

**Table 3.** The research programme of verification tests for the hernioplasty and vaginoplasty knitted implants.

| No. | Verification parameter   | Testing methods   | Identification of acceptance level for risk [16]:   |
|-----|--|---|---|
| 1.  | Surface mass   | PN-EN 12127:2000  | - High "foreign body" inflammatory reaction;<br>- Improper mechanical properties;<br>- Improper connective tissue in-growth;<br>- Improper stiffness of the implant;<br>- Prolonged integration of the implant with surrounding tissue. |
| 2.  | Thickness with the one-side surface expansion                              | PN-EN ISO 5084:1999   | - High "foreign body" inflammatory reaction;<br>- Improper connective tissue in-growth;<br>- Uncontrolled curling of the implant edge;<br>- Prolonged integration of the implant with surrounding tissue.                               |
| 3.  | Tensile strength in longitudinal or vertical direction                     | PN-EN ISO 13934-1:2002  | - Improper mechanical properties;<br>- Recurrence of the defects.   |
| 4.  | Elongation at break in longitudinal or vertical direction                  |   | - Improper mechanical properties;<br>- Recurrence of the defects;<br>- Uncontrolled curling of the implant edge;<br>- Absence of the biomimetics.   |
| 5.  | Suture pull-out in longitudinal, vertical direction as well as at a corner | Procedure based on ISO 7198:1998 [11]                                       | - Migration of the implant after implantation.  |
| 6.  | Bursting strength in the relation to the unit of circumference             | Procedure based on PN-EN ISO 12236:1998 using the semi-spherical stamp [11] | - Migration of the implant after implantation;<br>- Improper mechanical properties;<br>- Recurrence of the defects;   |
| 7.  | Replacement at 16 N/cm   |   | - Migration of the implant after implantation;<br>- Improper mechanical properties;<br>- Recurrence of the defects;<br>- Absence of the biomimetics.  |

**Table 4.** The research programme of verification tests for the knitted implants used for urinary incontinence treatment.

| No. | Verification parameter                                  | Testing methods        | Identification of acceptance level for risk [16]:   |
|-----|---|------------------------|---|
| 1.  | Linear mass   | PN-97/P-04613          | - High "foreign body" inflammatory reaction;<br>- Improper mechanical properties;<br>- Improper connective tissue in-growth;<br>- Improper stiffness of the implant;<br>- Prolonged integration of the implant with surrounding tissue. |
| 2.  | Thickness with the one-side surface expansion           | PN-EN ISO 5084:1999    | - High "foreign body" inflammatory reaction;<br>- Improper connective tissue in-growth;<br>- Uncontrolled curling of the implant edge;<br>- Prolonged integration of the implant with surrounding tissue.                               |
| 3.  | Tensile strength in longitudinal direction              | PN-EN ISO 13934-1:2002 | - Improper mechanical properties;<br>- Recurrence of the defects.   |
| 4.  | Elongation at break in longitudinal direction           |                        | - Improper mechanical properties;<br>- Recurrence of the defects;<br>- Uncontrolled curling of the implant edge;<br>- Absence of the biomimetics.   |
| 5.  | Initial modulus of elasticity in longitudinal direction |                        | - Recurrence of the defects;<br>- Absence of the biomimetics.   |

humidity of  $20\% \pm 5\%$  was stable during the study.

### Analytical methods

#### Implantable medical device testing

The physical properties of the designed knitted implants were verified before the acceleration study, as well as after stage I and stage II, to identify the possible changes and the range of changes.

The selection of the testing methods (research program) was performed based

on the risk analysis made according to the guide described in PN-EN ISO 14971:2009 Standard [16].

Testing of the physical properties was performed in an accredited Metrology Laboratory of the Institute of Biopolymers and Chemical Fibres. The scope of the verification is shown in **Tables 3 & 4**.

The number of samples of final products taken depended on suitable Standards requirements. The samples collected from



the product batches simulated the typical industrial manufacture of the medical devices (over 1000 pcs of final products for the acceleration ageing, biocompatibility studies and verification of the initial properties of final medical devices).

## Results and discussion

The research was carried out to verify the physical behaviour of the designed knitted implants after acceleration studies.

The obtained results of key features of the designed knitted implants were compared with the initially determined values.

### Verification of the performance and safety of the designed knitted implants

The knitted implant production range with the highest surface mass/linear mass was selected, as a tested variant for the verification of the changes in the physical properties of developed prototypes of medical devices (*the worst case* in accordance with the guidelines MEDDEV guides).

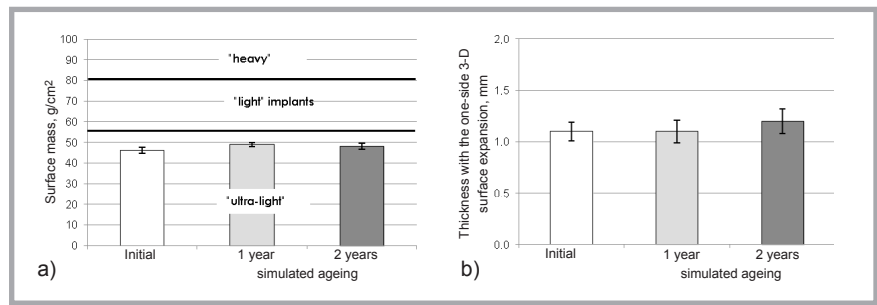
#### Knitted implants for hernioplasty and vaginoplasty

**Figure 1** shows the alteration in the surface mass during the acceleration of ageing with the marketed sections of “heavy” implants (surface mass  $> 80 \text{ g/m}^2$ ), “light” implants ( $80 \text{ g/m}^2 \geq$  surface mass  $\geq 55 \text{ g/m}^2$ ) and “ultra-light” implants (surface mass  $< 55 \text{ g/m}^2$ ). The newly-designed knitted implants were classified into the ultra-light group as they have a surface mass that is significantly lower than  $55 \text{ g/m}^2$ .

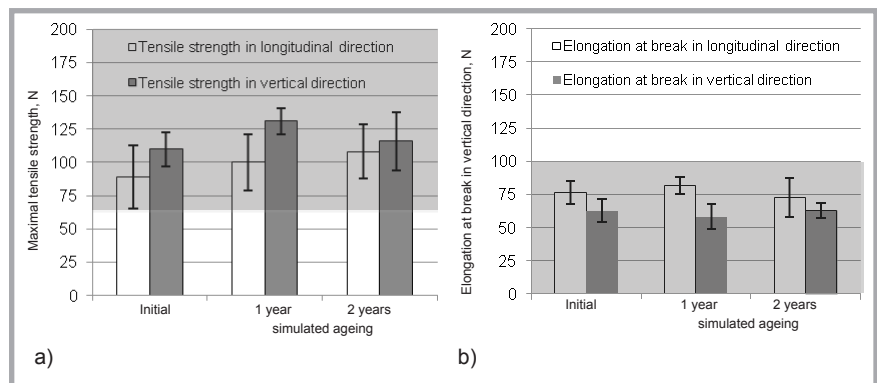
Surface mass of the newly-designed medical devices increased slightly with the prolongation of accelerated aging. The above phenomena can be explained by the thermal shrinking of the knitted structures during accelerated ageing performed at  $60 \text{ }^\circ\text{C}$  that is not observed during actual storage at ambient temperatures.

The change in the thickness with the one-sided three-dimensional (3-D) surface expansion (in the form of loops with a height of 3 – 4 mm [14]) of the designed medical devices after accelerated ageing is shown in **Figure 2**.

Increases in the thickness of the proposed medical devices measured with one-sided expansion in the form of irregular loops



**Figure 1.** Alteration in: a) the surface mass and b) thickness with the one-sided 3-D surface expansion of knitted implants for hernioplasty or vaginoplasty after accelerated ageing with the surface mass ranges of heavy, light and ultra-light implants.



**Figure 2.** Alterations in tensile strength (a) or elongation at break (b) in the longitudinal or vertical directions of knitted implants for hernioplasty or vaginoplasty after accelerated ageing; shaded area - range of the anatomical requirement.

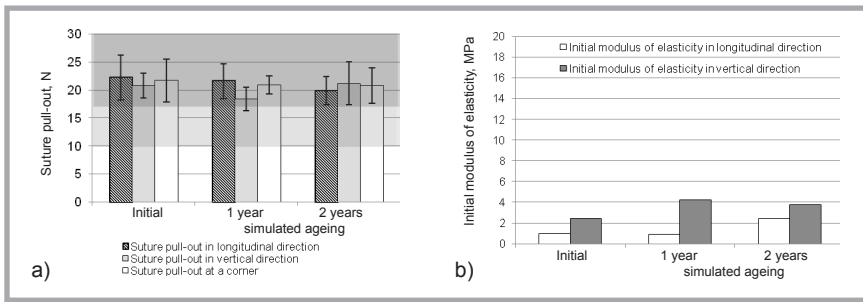
at the time of research into accelerated aging may be explained with a negligible increase in surface mass, as a result of thermal shrinkage of knitted fabrics. The flattening of the implants due to stable pressure of the backing of the packaging system was not confirmed. The above observations confirm the complete compatibility of the packaging system and the newly-designed implants.

In the process of accelerated ageing, the increase in tensile strength, both in longitudinal and transverse directions was observed (**Figure 2.a**). All of the values of maximal tensile strength were above 60 N (minimum level resulted from the anatomical requirements) in both the initial sample and after a period of 1 or 2 years of simulated storage under accelerated conditions. Taking into account the anatomical requirements, the higher tensile strength of implants results in the reduced risk of the breaking impacted by the continuous or temporary action of intra-abdominal pressure (of significant importance for implants used in hernioplasty) [17 - 20].

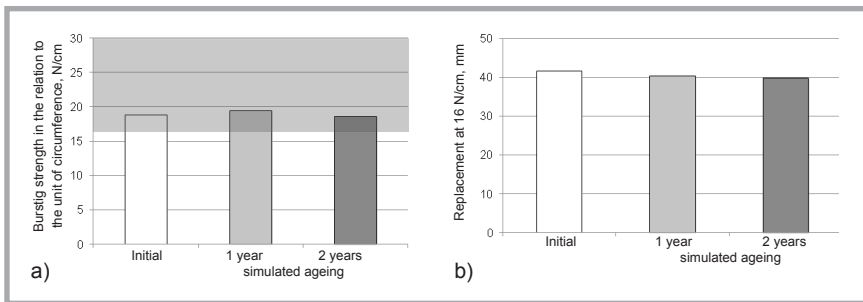
The elasticity of the implants used in general surgery as hernia patches as well

as in urogynaecology for the reconstruction of the vaginal wall is the most important factor with regard to biomimetic behaviour (**Figure 2.b**). Too high elasticity of an implant causes a high risk of improper reconstruction of defects in connective tissue, whereas the implants with low elasticity are not susceptible to anatomical movement of structures of the abdomen or vagina. The elaborated knitted implants are characterised as close to the optimal properties with regard to the elongation behaviour during the acceleration tests. A non-significant reduction in elongation in the longitudinal direction after 2 years of simulated storing was observed with an increase in the standard deviation. The above phenomenon can be connected to thermal changes in the macro- as well as microstructures of the newly-designed knitted implants.

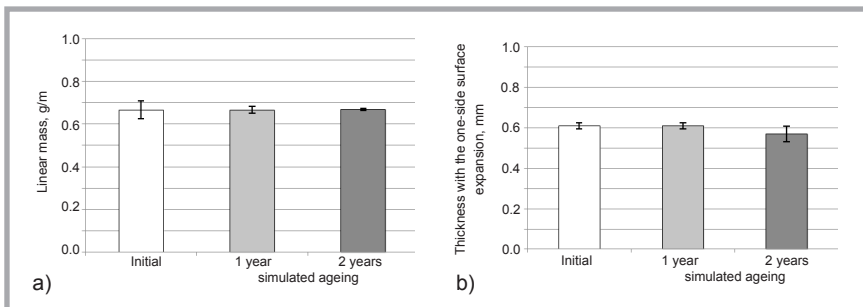
The suture pull-out described the resistance of the implants against uncontrolled migration due to damage to the fixations. The structure of the designed knitted implants (which enhance the one-sided surface in the form of the irregular loops) supports the connective tissue in-growth and, in the case of hernioplasty, the proposed implants are able to be fixed only



**Figure 3.** Alteration in: a) suture pull-out and b) the initial elasticity modulus in longitudinal or vertical directions as well as at the corners of knitted implants for hernioplasty or vaginoplasty after accelerated ageing;  - range of the anatomical requirements for hernioplasty,  - range of the anatomical requirements for vaginoplasty.



**Figure 4.** Alterations in: a) bursting strength per circumference and b) replacement at 16 N/cm of knitted implants for hernioplasty and vaginoplasty after accelerated ageing.



**Figure 5.** Changes in a) linear mass and b) thickness of knitted implants for urinary incontinence treatment after accelerated ageing.

by the punctual, resorbable suture. The surrounding structures of the abdomen also support the proper positioning and stabilisation of implants due to the pressure of abdominal viscera. On the other hand, the stabilisation of the implants during the reconstructions of the vaginal wall is crucial for proper clinical results.

Taking into account the above, as well as the anatomical requirements, the most crucial limitation of the suture pull-out for the hernia implants is a value higher than 10 N, whereas for the implants applied in urogynaecology is higher than 17 N.

**Figure 3.a** presents the changes in suture pull-out in longitudinal and vertical directions as well as at the corners of the

knitted implants during accelerated ageing.

The process of accelerated ageing was found to result in a non-significant decrease in the suture pull-out values (in the range of 0 – 11% depending on the stage of the acceleration test as well as the localisation of the measurement) in comparison with the initial data.

The changes in the initial elasticity modulus in the longitudinal and vertical directions of the newly-designed knitted implants are shown in **Figure 3.b**.

The initial elasticity modulus determines the rigidity of the designed medical device that moves the surgical handling of the implant after implantation and its

exact match to the vaginal wall or fascia to ensure the success of the reconstruction procedure. The accelerated ageing results in a slight increase in the initial modulus of the elasticity that causes an insignificant increase in stiffness of the elaborated knitted implants.

**Figure 4.a** shows the changes in bursting strength per circumference of knitted implants after accelerated study.

The susceptibility of the hernia implant to abdominal pressure is the most important factor selecting the proper design of this medical device. As described in [21 - 23], the anatomical limitation of bursting strength acting on the implant is no higher than 16 N/cm. This parameter is helpful in the determination of implants for vaginoplasty susceptibility to deformation as a result of the pressure of the surrounding tissue structure on them.

The accelerated tests show slight changes in bursting strength per circumference that do not influence the performance and safety of the designed implants, even after 2 years of simulated ageing.

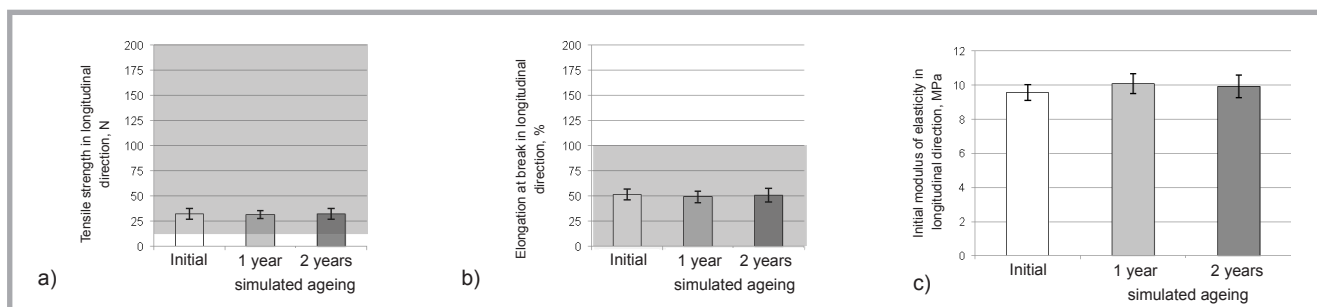
The replacement at 16 N/cm characterises the multi-directional susceptibility of the implant for the deformation originating from the abdominal pressure (hernia implant) or three-dimensional tension of the surrounding tissues. It also reflects the possible biomimetic features of the designed implants. The changes in these parameters were compared with the initial data in **Figure 4.b**.

The slight decrease in replacement at 16 N/cm after accelerated ageing was observed after both 1 and 2 years of simulated storage. The observation suggests compatibility with changes in surface mass and thickness, as well as elongation. The level of the changes did not affect the targeted performance or the safety of the implants.

#### **Knitted implant used for the urinary incontinence treatment**

The changes in linear mass of the designed knitted tape for urinary incontinence treatment during the acceleration study are shown in **Figure 5.a**.

In the case of aged knitted tape for urinary incontinence treatment, the linear mass was stable even after 2 year of simulated ageing. In conclusion, the changes in surface mass or linear mass are prob-



**Figure 6.** Changes in: a) tensile strength, b) elongation at break and c) the initial modulus of elasticity in the longitudinal direction of knitted implant for urinary incontinence treatment after accelerated ageing;  - range of the anatomical requirement.

ably connected to the macrostructure of knitted fabrics rather than to the changes in polymer structure.

The effect of accelerated ageing on the thickness of the knitted tape is shown in **Figure 5.b**.

The thickness of the newly-designed implants was slightly reduced after 2 years of simulated ageing. This observation may be combined with the flattening of the loops forming the 3-D structure and their more compact adherence to the implant surface.

The absence of detectable changes in the tensile strength in a longitudinal direction after the process of accelerated ageing of prototypes of knitted implants for urinary incontinence treatment was found in comparison with the initial data (**Figure 6.a**). The same phenomenon was observed when the elongation at break parameter was determined after the process of ageing (**Figure 6.b**). Moreover, it can be concluded that the lower tensile strength of the newly-designed knitted tape for urinary incontinence treatment as compared with the data for hernioplasty and vaginoplasty implants (**Figure 2.a**) is still within the safety range. The forces temporarily act on the urinary implants and are only associated with the procedure of surgical introduction of an implant, where the force does not exceed the value of 10 N.

The effect of accelerated ageing for the initial modulus of elasticity in a longitudinal direction of knitted implants for urinary incontinence treatment is presented in **Figure 6.c**.

The initial tensile module reflects the rigidity of the newly-designed implant associated with surgical handling and biomimetic features. Too rigid an implant may stiffen the implant location, contrib-

uting to patient discomfort. In addition, the high rigidity of the product threatens the loss of nesting efficiency, which can introduce a risk of perioperative complications as well as other adverse effects. In some limited cases, tape that is stiff can cut into the surrounding tissue during implantation. On the other hand, materials that are too elastic result in uncontrolled rolling-up and curling on the edges, allowing the accumulation of seroma.

The acceleration of ageing caused a slight increase in the elasticity modulus of the newly-designed knitted tape on a level that did not influence the performance or the safety of the newly-designed medical device.

## Conclusions

The designed knitted implants can be classified in the group of ultra-light medical devices as they have a surface mass that is significantly lower than 55 g/m<sup>2</sup> (for hernioplasty and vaginoplasty) or a linear mass lower than 0.7 g/m. The reduction in the amount of the monofilament (by applied structure as well as the monofilament with as low a mass as possible) did not result in a decrease in the mechanical strength below the anatomical requirements. The elaborated designs of knitted implants improve the biomimetic behaviour that is required for the novel implants.

The results of the accelerated ageing carried out on the prototype of ultra-light implants for hernioplasty, vaginoplasty and the urinary incontinence treatment modified by low temperature plasma of low molecular weight fluoroorganic compounds confirmed their performance and safety, in the scope of the physical

properties, during a maximum time of 2 years of storage in standard conditions.

The studies allow the evaluation of the acceptability of risk in terms of the stability of performance (physical properties) and confirmed the safety of the prototypes of ultra-light knitted implants in an assumed period of usefulness. Due to the validation and the possibility of negative effects of thermal degradation, the obtained results should be compared with the data obtained during ageing under real conditions.

## Acknowledgments

The research was carried out within developmental project No. N R08 0018 06 "Elaboration of ultra-light textile implants technology for using in ureogynecology and in the procedures of hernia treatments" funded by the National Centre for Research and Development.

## References

- 1 Fricke H, et al. *Flat implant made of textile thread material, particularly a hernia mesh*. US 2005/0228408 A1, 2003.
- 2 Thierfelder C, et al. *Implantable article and method*. US 6592515, 2003.
- 3 Enrico N. *Hernia prosthesis*. EP 1200010, 2000.
- 4 Alvarado A. *Laparoscopic Inguinal Hernia Prosthesis*. US 2006/0015143, 2006.
- 5 Simmoteit R, et al. *Implant and method for producing*, JP 2003062062, 2003.
- 6 Bielecki S, et al. *A biomaterial composed of microbiological cellulose for internal use, a method of producing the biomaterial and the use of the biomaterial composed of microbiological cellulose in soft tissue surgery and bone surgery*. US 2003 100955, 2007.
- 7 Struszczyk MH. *Innovative surgery nets for supplying connective tissue loss* (in Polish). Scientific Letters Ed. Lodz University of Technology No. 1005, 2007.
- 8 ASTM F1980:2002 Standard guide for accelerated ageing of sterile barrier systems for medical devices.

- 9 Kucharska K, Struszczyk MH, Cichecka M, Brzoza-Malczevska K, Wiśniewska-Wrona M. Prototypes of Primary Wound Dressing of Fibrous and Quasi-Fibrous Structure in Terms of Safety of their Usage. *FIBRES & TEXTILES in Eastern Europe* 2012; 20, 6B (96) 142-148.
- 10 Struszczyk MH, Gutowska A, Kowalski K, Kopias K, B Palys, Komisarczyk A, Krucińska I. Ultra-light knitted structures for application in urologinecology and general surgery, – optimisation of structure in the aspect of physical parameters. *FIBRES & TEXTILES in Eastern Europe* 2011; 19, 5 (88): 92-98.
- 11 Struszczyk MH, Komisarczyk A, Krucińska I, Kowalski K, Kopias K. Ultra-light knitted structures for application in urologinecology and general surgery – optimization of structure. *FiberMed11* 28-30 June 2011, Tampere, Finland, ISBN 978-952-15-2607-7.
- 12 Kostanek K, Struszczyk MH, Domagała W, Krucińska I. Surface modification of the implantable knitted structures for potential application in laparoscopic hernia treatments. *FiberMed11* 28-30 June 2011, Tampere, Finland, ISBN 978-952-15-2607-7.
- 13 Struszczyk MH, Kostanek K, Puchalski M, Krucińska I. Design aspects of fibrous, implantable medical devices. In: *Proceedings of EGE MEDITEX-2012 International Congress on Healthcare and Medical Textiles*. ISBN 978-975-483-953-1, May 17-18, 2012 Izmir, Turkey.
- 14 Struszczyk MH, Kopias K, Kowalski K, Golczyk A. Trójwymiarowy, dziany implant do rekonstrukcji ubytków tkanki łącznej. Pat. Appl. PL P-394623, 2011.
- 15 Kostanek K, Struszczyk MH, Krucińska I, Urbaniak-Domagała W, Puchalski M. Sposób modyfikacji trójwymiarowego implantu do zaopatrywania przepuklin w zabiegach małoinwazyjnych. Pat. Appl. PL P-395988, 2011.
- 16 Struszczyk MH, Kowalski K, Kopias K, Komisarczyk A. Aspects of risk analysis in the design of knitted medical devices for use in general surgery and urologynaecology (in Polish). In: *IX Międzynarodowa konferencja naukowo-techniczna Knitt Tech 2010*, 17-19.06.2010, Rydzyna, 2010.
- 17 Nilsson T. Biomechanical studies of rabbit abdominal wall. Part I. The mechanical properties of specimens from different anatomical positions. *J. Biomech* 1982; 15, 2: 123-9.
- 18 Neugebauer R, et al. Die Bauchdeckenersatzplastik Durch Ein Unbeschitetes Kohlenstoffgewebe. *Langebecks Arch. Chir* 1979; 350: 83-93.
- 19 Bellon JM, et al. Improvement of the tissue integration of new modified polytetrafluoroethylene prosthesis: MYCRO MESH. *Biomaterials* 1996; 17: 1265-1271.
- 20 Meddings RN. A new bioprosthesis in large abdominal wall defects. *J. Pediatr. Surg* 1993; 28: 660-663.
- 21 Trauler R, bedeutung mechanischer faktoren bei der entstehung der abdominalen wunddehiszenz, *Zentrbl. Chir* 1975; 19: 1178-1182.
- 22 Klinge U, et al. Pathophysiology of abdominal wall. *Chirurg* 1996; 67: 229-233.
- 23 Schumpelick V, et al. Minimierte polypropylene-netze zur praepéritonealen netzplastik (PNP) der narbenhernia. *Chirurg* 1999; 70: 422-430.

Received 02.11.2011 Reviewed 04.04.2012



## INSTITUTE OF BIOPOLYMERS AND CHEMICAL FIBRES LABORATORY OF PAPER QUALITY

Since 02.07.1996 the Laboratory has had the accreditation certificate of the Polish Centre for Accreditation No AB 065.

The accreditation includes tests of more than 70 properties and factors carried out for:

- pulps
- tissue, paper & board,
- cores,
- transport packaging,
- auxiliary agents,
- waste, wastewater and process water in the pulp and paper industry.



AB 065

The Laboratory offers services within the scope of testing the following: raw -materials, intermediate and final paper products, as well as training activities.

### Properties tested:

- general (dimensions, squareness, grammage, thickness, fibre furnish analysis, etc.),
- chemical (pH, ash content, formaldehyde, metals, kappa number, etc.),
- surface (smoothness, roughness, degree of dusting, sizing and picking of a surface),
- absorption, permeability (air permeability, grease permeability, water absorption, oil absorption) and deformation,
- optical (brightness ISO, whiteness CIE, opacity, colour),
- tensile, bursting, tearing, and bending strength, etc.,
- compression strength of corrugated containers, vertical impact testing by dropping, horizontal impact testing, vibration testing, testing corrugated containers for signs „B” and „UN”.

### The equipment consists:

- micrometers (thickness), tensile testing machines (Alwetron), Mullens (bursting strength), Elmendorf (tearing resistance), Bekk, Bendtsen, PPS (smoothness/roughness), Gurley, Bendtsen, Schopper (air permeance), Cobb (water absorptiveness), etc.,
- crush tester (RCT, CMT, CCT, ECT, FCT), SCT, Taber and Lorentzen&Wettre (bending 2-point method) Lorentzen&Wettre (bending 4-point method and stiffness rezonanse method), Scott-Bond (internal bond strength), etc.,
- IGT (printing properties) and L&W Elrepho (optical properties), etc.,
- power-driven press, fall apparatus, incline plane tester, vibration table (specialized equipment for testing strength transport packages),
- atomic absorption spectrometer for the determination of trace element content, pH-meter, spectrophotometer UV-Vis.

### Contact:

INSTITUTE OF BIOPOLYMERS AND CHEMICAL FIBRES  
ul. M. Skłodowskiej-Curie 19/27, 90-570 Łódź, Poland  
Elżbieta Baranek Dr eng. mech.,  
tel. (+48 42) 638 03 31, e-mail: elabaranek@ibwch.lodz.pl