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Aspects of Chemical Characterisation of Leachables Profile from Ultra-Light Knitting Textiles for Uses as Medical Implants in Urogynaecology and General Surgery

Abstract
Ultra-light textiles (knitwear) designed as implantable medical devices for potential uses in urogynaecology (treatment procedures in women incontinence and vagina reconstructions) and general surgery (hernia treatments) are a response to the increasing demand for advanced medical devices in medicine. Chemical profile characterisation of leachable substances is an important factor in the use of the materials influencing their biocompatibility. The implant is made of undesired chemical substances in the main raw-material, and penetration into the tissue may cause local and/or systemic inflammation in the patient's body. The characterisation and analysis of such substances is therefore essential to secure the safe use of implants. Most important is the characterisation of the matter that is extractable from the designed medical devices. To serve these purpose, ultra-light textile implants designed for potential use in urogynaecology and general surgery were examined concerning the chemical analysis of the undesired substance contained in the main material which constitutes the base of the implant. It was a goal of the work to set optimal parameters for the examination of chemical characterisation of the leachable implant's material, bearing in mind their safe clinical use. Analysis of the chemical leachable profile was made in accordance with directives of standard PN-EN ISO 10993-18:2008 and some Polish and European testing procedures.

Key words: *ultra-light textile implants for urogynaecology, evaluation of chemical leachable profile, physical-chemical parameters.*

Introduction

Investigation of advanced textiles for medical uses is one of the priorities in worldwide research. The herein reported work presents part of a wider research study in ultra-light textile knitting implants designed for use in urogynaecology (procedures in women's incontinence, repair of the female genital system) and general surgery (procedures in hernia treatments).

Incontinence is estimated to afflict 10-15% of the population, depending on race, ethnic groups, and the environment, with women comprising the majority. Incontinence can occur at any age with a frequency of about 30% of women, surpassing hypertension (21%), depression (20%) and diabetes (9%). Four million people in Poland are estimated to suffer from incontinence, and the annual cost of protective products for those affected amounts to 400 m PLN (about 90 m Euros), while in the States the expense reaches 15 bn USD [1]. In the U.K., 2% of the health budget goes toward incontinence [2, 3]. 8000 incontinence operations were performed in the period 2000-2001, incurring a cost of 10.3 m GBP [4, 5].

Incontinence can occur as a steady or continual ailment, largely exacerbating the quality of life. It may, in those afflicted, be the cause of a serious psychophysical disorder and limit their functioning in society, even causing possible isolation [1].

Uterus prolapse afflicts one in four women after the age 40 years. Frequent childbirth, a large foetus, long periods of work in a standing position, obesity, chronic coughs as a result of chronic obstructive pulmonary disease (COPD) and smoking are risk factors for the disease. The presently applied repair involves gynaecological lifting surgery with the use of knitting implants. The textile implant replaces the latae muscles and broken fascia and joints in the pelvis, and integrates itself with the newly growing tissue. With the use of the implant, the uterus is lifted into its original anatomic position. One other surgical operation is the front or hind vaginoplasty, with the introduction of a polypropylene textile band. An overgrowing of the implant with the patient's tissue is assumed in the operation [6].

Hernia repair is trivial in general surgery worldwide. The most common hernias by far occur in the abdomen. A hernia is the protrusion of tissue or an organ in part or in whole from its normal anatomic position. Countless hernia repairs performed annually in the world are a problem, not only medically but also economically.

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Therefore, advanced operating techniques and new medical devices for hernia repair are still sought. Investigations are also under way to better detect the reasons for hernia occurrence [5, 7 - 9].

The assumption of research in the preparation of biomimetic ultra-light knitting implants for surgery is a response to the important social problem [10].

The presented research, including the chemical leachable profile determination, is the next step of the design of ultra-light textile implant technology for use in ureogynaecology and in the procedures for hernia treatment. During the initial stage [10], the evaluation of biomechanical properties accounting the pathophysiological behaviour of designed variants of implantable medical devices was performed.

Due to their destination, the ultra-light polypropylene textile implants are classified as class IIb: invasive medical devices for permanent use (over 30 days) in contact with soft tissue and internal organs, according to the classification outlined in the Council Directive 93/42/EWG, 14 June 1993.

Ultra-light textile implants for potential use in surgical procedures must be subjected to the biological evaluation in the range of leachable profile according to general guides of Standards PN-EN ISO 10993-18:2009 [14], PN-EN ISO 10993-12:2009 [15] and PN-EN ISO 14630:2009 [16]. The above-mentioned documents do not identify acceptable levels of leachable chemicals or that it is necessary to perform scopes for the leachable materials, but instead provides initial and general indications. In addition, some general guidelines for the elaboration of the research programme were provided, mainly based on a risk analysis carried out in accordance with the guidelines PN-EN ISO 14791:2011.

In this research project, which is related to the chemical characterisation of leachable materials from ultra-light knitwear designed for implantable medical devices used in urogynaecology and general surgery, the characteristics of extractable substances were tested as an extension of the research and analysis of biomechanical properties reported in an earlier publication [10].

A testing methodology was prepared enabling the evaluation of the profile of extractable (leachable) substances under the conditions of a simulated, clinical use (specification of the processing conditions, nature and contact time of the designed implant), whereas the investigation scope (selection of parameters and the acceptable limits) was determined on the basis of conclusions from the initially prepared risk analysis [21], and the main tools for designing the optimal investigation roadmap of the research.

The quantitative and qualitative evaluation of leachable materials from medical devices, as the main results of the present study, allows outputs to be provided for biological response evaluation (as a verification stage) and for estimation of safety and performance during clinical validations (as a clinical study).

Materials

The characteristics were examined of leachable substances in three-dimensional, ultra-light textile knitwear, coded as follows:

- ***SP1*** - three variants with surface density of: 31.3 ± 2.4 g/m^2 (SP1-35), 47.9 ± 1.6 g/m^2 (SP1-43) or 45.6 ± 2.5 g/m^2 (SP1-48);
- ***SP2*** - two variants with surface density of: 25.5 ± 2.4 g/m^2 (SP2-27) or 34.4 ± 3.5 g/m^2 (SP2-35);
- ***SP3*** - two variants with surface density of: 26.8 ± 1.2 g/m^2 (SP3-44) or 40.0 ± 2.2 g/m^2 (SP3-49).

These were prepared according to procedures described elsewhere [10, 17, 22]. The structures of the investigated samples are shown in ***Table 1*** [10, 22].

The physical characteristics of all elaborated knitwear were previously described in more detail [10, 17, 22].

The characteristics of the extractable substances was also determined for the starting material: medical grade polypropylene monofilament with 0.08 mm diameter (46 dtex) (class VI acc. to US Pharmacopeia), which served as a reference for the tested materials.

Table 1. *The structures of the raw 3-D knitted fabrics (SP1 to SP3 variants) [10, 22].*

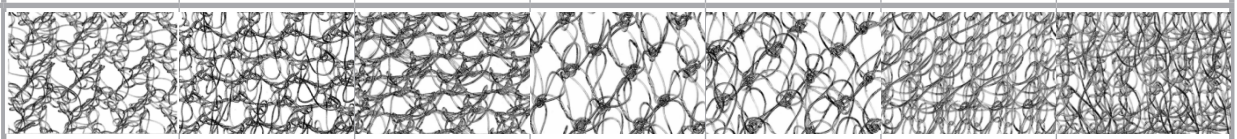
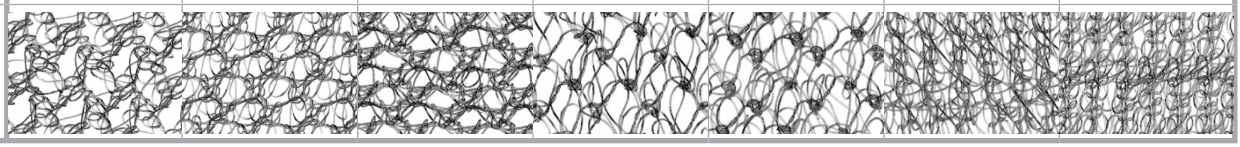
Tested sample	SP1			SP2		SP3	
	Variants						
	35	43	48	27	35	44	49
Flat side							
Side with 3-D stitched loops							

Table 2. *Chemical characterisation of leachable profile of an aqueous extract from PP-M.*

pH of aqueous extract	Content of heavy metals [mg/100cm^3 aqueous extract]						Permanganate oxygen consumption, mgO_2/g of medical device	Content of [Cl]$^-$, mg/g of medical device product	Turbidity of the aqueous extract, NTU
	Al	Cd	Cr	Pb	Zn	Hg			
6.5	< 0.005	< 0.002	< 0.02	< 0.02	< 0.001	< 0.0002	0.15	0.63	4.0

The other physical characteristics of the raw materials used have been presented previously [10, 22].

The main characteristics of the extractable substances of the polypropylene monofilament (PP-M) are shown in ***Table 2*** and ***Figure 1***. The aqueous extract of PP-M was prepared in the ratio of 10 g of the material (monofilament)/100 cm^3 water. The extraction was performed in an autoclave at 121 °C for 30 minutes.

Aqueous extracts were prepared based on Standard PN/P-04894:1984 and in accordance with directives of Standard PN-EN ISO 10993-12:2009. The extracts were evaluated in respect to the chloride anion content (PN/P-04895:1984 Standard), permanganate oxygen consumption (PN/P-04896:1984 Standard), turbidity (Polish Pharmacopeia VII), pH of extract (PN-EN ISO 3071:2007 Standard), content of water-soluble substance (PN/P-04781/06:1988 Standard) and content of heavy metals (testing procedure IBWCh NL-13/2008 issue IV, 2008). The 3-step extraction was performed according to Standard PN-EN ISO 10993-12:2009 [15].

Methodology

Standard PN-EN ISO 10993-12:2009 [15] was applied in the investigation related to the leachable substance profile evaluation of ultra-light knitwear designed for implantable medical devices for uses in urogynaecology or general surgery.

Exhaustive extraction at 121 °C and pressure of 1 atm for 40 minutes was selected based on the indication described in [15] to simulate the steam-sterilisation process and to evaluate the amount of water-extractable substances that can be realised during the final technological process.

10 g of the examined medical device in 100 cm^3 of water was used in the extraction. The implants were prepared in two replications. The pH of the aqueous extract, content of chloride ions, turbidity, content of surfactants, content of heavy metals, content of $[NH_4]^+$ ion, total content of water-soluble substance and permanganate oxygen consumption were analysed in the aqueous extract.

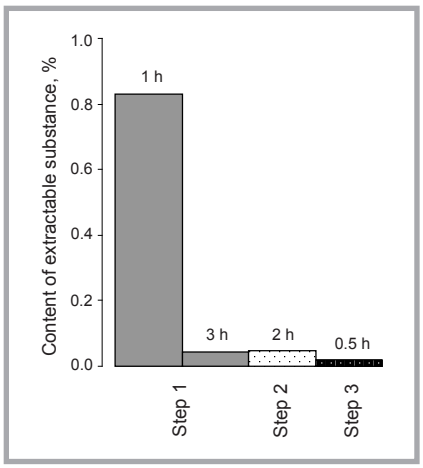


Figure 1. *Quantitative characteristic of substances extractable from PP-M in a multistep extraction: Step 1 - petroleum ether; Step 2 - isopropanol; Step 3 - purified water.*

Samples of the implants were also 3-stepwise exhaustively extracted with non-polar solvent-petroleum ether to determine the optimal extraction time needed to remove the maximum amount of the processing aids, for example: spin finish used in the course of preparing the implant prototypes. The products were also extracted with the polar solvent – propanol-2 and pure water in a similar way to get the maximum yield of the leachable substance from the tested materials.

Analytical methods

Turbidity, content of chloride ions, presence of reductive substances, pH of aqueous extracts and content of heavy metals ions were estimated in the prepared aqueous extracts. The amount of substance deposited on the product during processing or the remaining portion of oligomers and monomers was estimated in the organic solvent extracts.

Turbidity

The turbidity (transparency) of the aqueous extracts was estimated according to a spectrophotometric method prepared based on a visual method contained in the Polish Pharmakopeia VII (2005).

pH of the aqueous extract

The pH of the aqueous extracts was measured using a potentiometric method with LAB 860 SET apparatus electrode BluLine 14 pH equipped with an integrated temperature sensor (Scott Cowith). The apparatus is devised for measurements in clear fluids with small amount of sediment in the pH range of 0 - 14. Measurements were performed according to Standard PN-EN ISO 3071:2007.

Reducitve substance

The content of reductive substances (permanganate oxygen consumption) was estimated according to Standard PN-P-04896:1984.

Content of $[Cl]^-$ ions

The content of chloride ions was estimated according to Standard PN-P-04895:1984. The applied method consists of argentometric titration of the prepared aqueous extracts with an $AgNO_3$ solution at concentration of 0.01 mol/dm^3 in the presence of chromate ions.

Content of heavy metals

The estimation of heavy metal ion content was made according to a method applied in an accredited laboratory [21]. Atomic Absorption Spectroscopy (AAS) was harnessed to this end with the use of SCAN-1 apparatus (ThermoJawell ASH Co.) to determine the content of Cd, Cr (jointly all oxidation levels), Pb, Zn and Hg. Cd, Cr, Pb and Zn were also determined in the aqueous extracts by the flame method ASA (FAAS*) using the following parameters:

- Cd: wave length λ = 228.8 nm, acetylene-air flame, limit of measurability 0.02 mg/dm^3;
- Cr: wave length λ = 357.9 nm, acetylene-N_2O flame, limit of measurability 0.2 mg/dm^3;
- Pb: wave length λ = 217.0 nm, acetylene-air flame, limit of measurability 0.2 mg/dm^3;
- Zn: wave length λ = 213.9 nm, acetylene-air flame, limit of measurability 0.01 mg/dm^3.

Mercury was estimated by the Flow Injection Cold Vapour Atomic Absorption ASA (CVAAS***) method using the Atomic Vapour Accessory 440 (ThermoJawell ASH Co.) to generate the cold vapours.

Parameters of the analysis of Hg were as follows: wavelength λ = 253.7 nm, reductive solution 5% $SnCl_2$ in 20% HCl, carrier gas Ar, limit of measurability 0.002 mg/dm^3.

Aluminium was estimated by atomic absorption spectroscopy with electro-thermal atomization (ETAAS***).

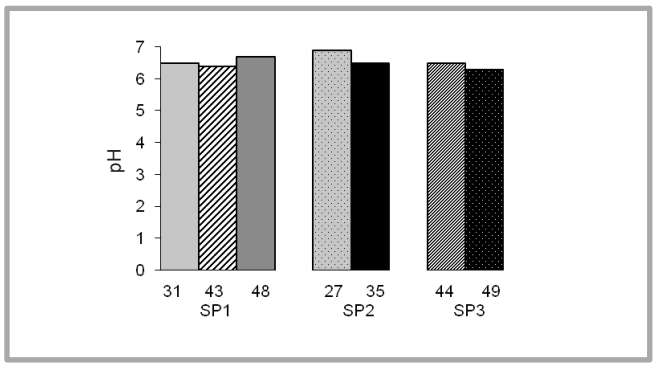


Figure 2. *pH of aqueous extracts of SP1, SP2 or SP3 variants of knitted implants.*

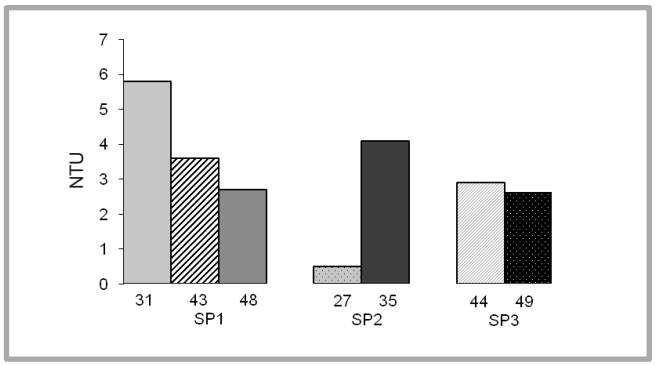


Figure 3. *Turbidity of aqueous extracts from SP1, SP2 or SP3 variants of knitted implants.*

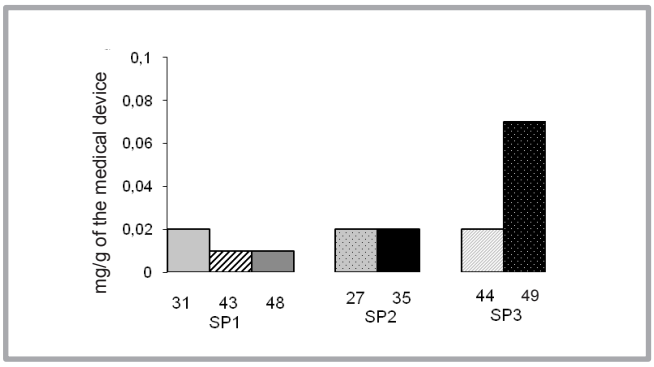


Figure 4. *Content of chloride ions in the aqueous extracts from SP1, SP2 or SP3 variants of knitted implants.*

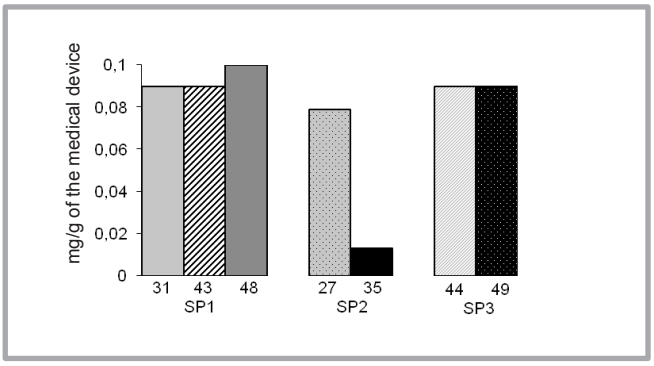


Figure 5. *Content of reductive extractable substance extracted from SP1, SP2 or SP3 variants of knitted implants.*

3-step extraction

The content of substances that are leachable from the implant prototypes was estimated by an exhaustive extraction first with petroleum ether and then with propanol-2 in Soxhlet apparatus according to the directives of Standards PN-EN ISO 10993-12:2009 and PN/P-04607:1983 with a synergic action on the implants of substances showing different polarities.

Water dissolvable substances were estimated according to the method of Standard PN-P-04781/06:1988.

Results and discussion

The results of the determination of selected parameters which may have a direct impact on the safety of textile implants in urogynaecology and general surgery are presented in the work, particularly in terms of biological compatibility.

The range of research has been estimated based on the results from the initially-prepared risk analysis [21] accounting for the assumed processing conditions, time and nature of the contact of the designed implants, as well as information from the material investigations. The results of properly elaborated risk analysis were essential and helpful to elaborate research programmes indicating a roadmap to evaluate the leachable chemical profiles of designed implants.

The results of the chemical characterisation of the extractable substances for all variants of SP1, SP2 or SP3 with different surface density are presented below.

pH of aqueous extracts

The results of pH estimation of aqueous extracts of SP1, SP2 or SP3 differing in surface density are shown in ***Figure 2***.

The pH of aqueous extract values of implant prototypes vary in the range from 6.3 to 6.9, which is the optimal range for aqueous extracts of this kind of medical devices.

An aqueous extract pH significantly below 5.0 and above 8.0 is able to affect medical devices, mostly by causing irritation.

Turbidity of the extracts

Values of turbidity for extracts of all variants of SP1, SP2 and SP3 implants are shown in ***Figure 3***.

According to recommendations of the Polish Pharmacopeia VI for medical devices, a solution is considered to be transparent if its turbidity does not exceed 6 NTU (*Nephelometric Turbidity Units)*.

It can be seen from the results presented that the lowest value of turbidity appears for sample SP2-27 (variant with the lowest surface density). Results for the SP1-48, SP2-35 and SP3-44 samples with surface densities of 45.6, 34.4 and 26.8 g/m^2, respectively, met the pharmacopeia's requirements.

It was found that the efficiency of purification of medical devices may depend upon the type of textile structure connected with the type of the splice, as well as the surface density of the implant prototype.

Content of chloride anions $[Cl]^-$

The chloride ion contents for the tested SP1, SP2 and SP3 implant variants are shown in ***Figure 4***.

The presented results testify that the extract of tested SP1 variants with a surface density of 47.9 g/m^2 (SP1-43) and 45.6 g/m^2 (SP1-48) showed the lowest

Table 3. *Content of heavy metal ions in the aqueous extracts prepared from SP1, SP2 or SP3 variants of knitted implants.*

Tested sample		SP1			SP2		SP3	
		Variants						
		31	43	48	27	35	44	49
Content of heavy metals, mg/100 cm^3 of the aqueous extract	Cd	<0.002	<0.002	<0.002	<0.002	<0.002	<0.002	<0.002
	Cr	<0.02	<0.02	<0.02	<002	<0.02	<0.02	<0.02
	Pb	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02
	Zn	0.00185	0.00246	0.00246	0.0093	0.0051	0.0075	0.0018
	Hg	<0.0002	<0.0002	<0.0002	<0.0002	<0.0002	<0.0002	<0.0002
	Al	<0.005	<0.005	<0.005	<0.005	<0.005	<0.005	<0.005

content of chloride ions (0.01 mg/g). However, the purity of the aqueous extracts of all implants are significantly lower than value obtained for the raw material – polypropylene monofilament (0.63 mg/g; ***Table 1***).

Reductive substance

The level of reductive substance in the aqueous extracts from SP1, SP2 or SP3 variants is presented in ***Figure 5***.

The analysis of reductive substances leads to the estimation of the content of organic and inorganic residues in the extracts from the tested medical device prototypes. It can be seen from the results that aqueous extracts were prepared with the content of reductive leachable chemicals not exceeding the value of 0.1 mg O_2/g calculated on the weight of the medical device, and is much below that of the starting raw-material - PP monofilament (0.15 mg O_2/g; ***Table 2***).

Content of heavy metal ions

The results of the examination of the content of heavy metal ions in the aqueous extracts prepared from SP1, SP2 and SP3 variants of knitted implants are presented in ***Table 3***.

It can be seen that the content of singular ions for both the PP monofilament and for all of the tested variants of medical device prototypes fall below the detection level of the ASA method.

Multistep extraction

The results of the examination concerning quantitative evaluation of the extractable substances obtained in a 3-step extraction with petroleum ether, propanol-2 and purified water for the variants of knitted prototypes of implants differing in surface density are presented in ***Figure 6***.

It can be noted from the obtained results that the level of the substance extracted in the consecutive steps does not exceed the permissible limits and is much lower than in the starting raw-material (PP monofilament; see ***Figure 1***).

It is known from the literature [19, 20] and the Polish Pharmacopeia that the permissible maximum amount of extractable substances in the medical devices is 2%. The quantitative composition is obviously important too with emphasis on the presence of leachable toxins.

Ultra-light textile implants, specially designed during the research, are a group of medical composites made up of medical grade polypropylene (PP) monofilaments (US Pharmacopeia – class VI). PP used for this purpose shows the lowest density, amongst the commercial so-called processing or auxiliary aids, i.e. containing only traces of auxiliary substances which are not significantly released into the environment. The above-mentioned aids do not undergo degradation in a biological environment. Equally important with regard to biocompatibility of the material with human tissue are the implant material surface parameters. A very careful selection of the chemical compo-

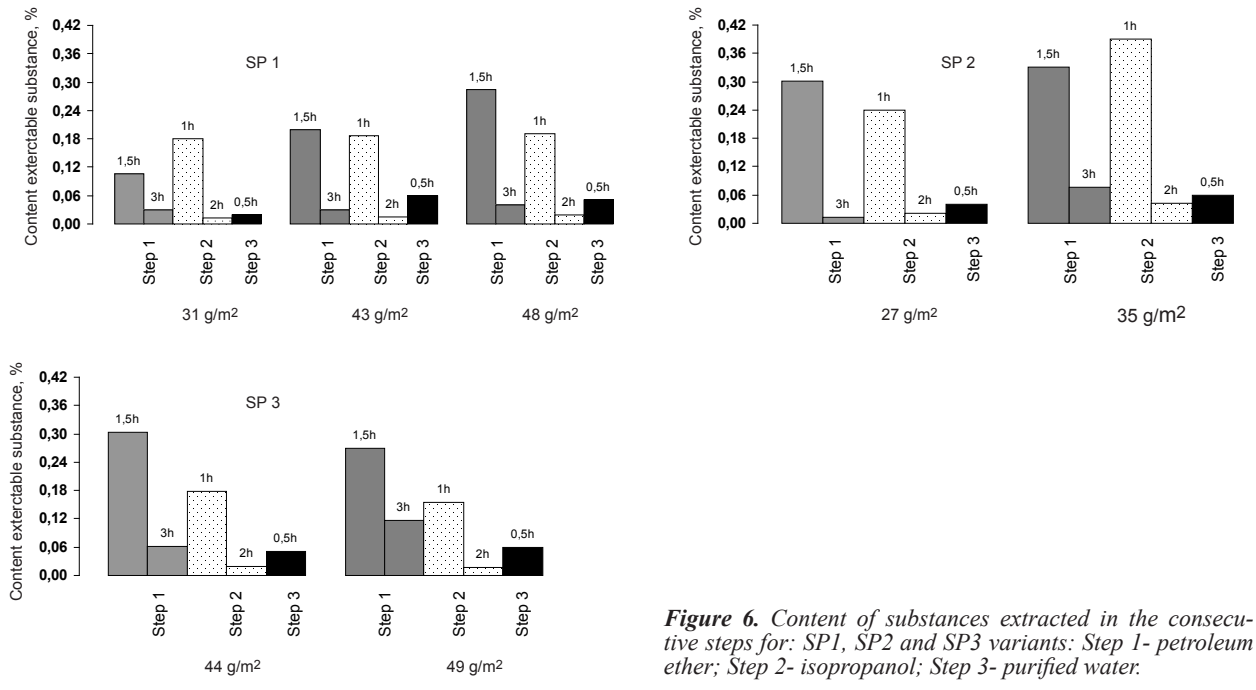


Figure 6. *Content of substances extracted in the consecutive steps for: SP1, SP2 and SP3 variants: Step 1- petroleum ether; Step 2- isopropanol; Step 3- purified water.*

sition of the used polymer (inclusive the quality and quantity of extractable substance - leachable) and the physical properties of the implant's surface, along with biological biocompatibility and the possible ability to stimulate tissue growth, are preconditions of the successful acceptance of the implant by the human body [11].

The yarns used usually contain processing aids and/or auxiliary substances in their mass and/or adhering to their surface. There are catalysts, activators, unreacted substrates, and elastomers to ease processing and finishes that confer secondary performance upon the fibre (whiteners, agents to improve resistance to UV radiation, spin finishes, antioxidants, etc). Such substances are undesired in medical devices.

Some substances may be generated in the course of processing (spinning of the fibre, sterilisation of the implants) as a result of:

- degradation of the polymer or its chemical destruction (e.g. oligomers, products of oxidative degradation),
- chemical reactions (such as derivatives of ethylene oxide in gaseous sterilisation or cross-linked polymers during irradiation sterilisation).

Despite the medical purity of the initial polymers, the medical devices in their final form may contain several permanently or loosely bonded chemical substances which, released during or shortly after the implantation or later as a result of the implant's degradation, may cause postoperative local, or more frequently, systemic complications.

A clinical trial conducted according to Standards PN-EN ISO 14155-1/2 [12, 13] is incapable of estimating the negative impact of substances that are leached out of the medical device, since the adverse effects often appear long after the implantation. The earlier identification of possible risks connected with the leachable chemicals from designed implants, as early as the preclinical stages of the design of implants, allows more effective analyses to be carried out.

Chemical substances settled on the fibre surface can be removed by various finishing techniques, like washing or extraction; however, the removal degree, varying depending upon the process used, the type of fibre (multifilament or monofilament) and the applied substance, never reaches 100%. Substances incorporated into the fibre mass are much more difficult to remove. Known techniques are ineffective and the substances may penetrate from the implant into patient over a long period of time.

During the risk analysis [21] the main hazards associated with the chemical purity (characterised as a chemical leachable profile) of elaborated variants of knitwear were identified and estimated as follows:

- inappropriate pH of aqueous extract – the pH of extracts outside the range of 5.0 – 8.0 results in several local adverse effects, such as irritation. Consequently, in the case of implants for the reconstruction of connective tissue, the formation of a massive scar around whole implants can yield several late complications, such as pain, stiffness of the abdominal wall, problems with breathing, etc.
- high turbidity of the aqueous extract, high content of extractable in polar and non-polar solvents are connected with an inappropriate leachable chemical profile of implants, resulting in the inappropriate elimination or removal (if applicable) of processing aids during manufacture of the implant. The above hazards originate directly from the process of raw-material selection as well as the process of manufacturing of the implants, which are the main stages that are responsible for the elimination of undesired processing aids.
- relatively high oxygenicity – the high amount of the reductive substances (organic or inorganic) affects the local irritation of the surrounding tissue, resulting in several undesired biological reactions, such as prolongation of the inflammation, irritation, inappropriate tissue remodelling, implant encapsulation as well as implant rejection.
- presence or high amounts of heavy metal ions - the physiological role of cadmium, mercury, and lead is not known, but metals are suspected to be toxic (both local and systemic toxicity). High amounts of the above-mentioned metals increase the risk of cancer formation, deformation of bones, destruction of metabolic routes, destruction of kidneys and bone tissue, pathomorphological changes in the liver, etc. and can be accumulated in several internal organs, such as the kidney, brain, liver, etc. Zinc, chromium or aluminium as microelements are safe if the amounts do not exceed the natural limits.
- high amounts of chloride ions, the inorganic or/and organic derivatives containing chlorine, are a component of the processing aids used in the manufacture and processing of yarns. The determination of high amounts of the above ions can affect the destruction of metabolic reactions.

Therefore, the identification and estimation of potential risks related to the inappropriate chemical composition of leachable chemicals (defined as the profile of potential substances extractable under simulated clinical conditions) is essential. It is of great importance to accomplish the estimation of the chemical profile of leachable substances under simulated conditions mimicking the processing, nature of the textile medical device and its contact time, as well as the nature of the contact with the human body.

Estimations made under conditions far from clinical use may result in a different profile of the leachable substances, leading to an underestimated risk of the postoperative complications that can be verified during biocompatibility studies, as well as those validated during the clinical studies [18, 19].

The presented research results summarise the data of leachable chemical profiles of designed prototypes of fibrous implants as the main inputs for the acceptance of the risk level of the identified hazards [21].

Conclusions

The investigation carried out on the chemical characterisation of leachable ultra-light polypropylene implants for application in urogynaecology and general surgery represents a basis to determine whether the purification was efficient and to evaluate changes that occur in the prototypes of textile implants during their processing.

It was found that the tested materials reveal a high chemical purity and that there are no major differences in the profiles of extractable substances between the prototype textile implants with different structures.

Insignificant differences in leachable profiles are allegedly related to different splices in the knitwear, the structures of which may facilitate or hinder the purification process. Knitwear with larger pores generally tends to deliver a lesser amount of the extractable substance. The above phenomenon can be explained by the better availability of the knitting structures with a lower surface density during the impurity removal process performed according to [22].

The best chemical purity was obtained for SP1 variants, which were mostly characterised by medium or low surface density (large pores). Moreover, the chemical purity of all of the elaborated prototypes was relatively high, and acceptable for implantable applications [19]. On other hand, the chemical profile of leachable substances are one of the aspects enabling selection of the optimal properties of designed implants, including biomechanical properties, biocompatibility, performance biostability, susceptibility to maintaining the assumed mechanical properties for a long time after application, resistance against sterilisation, as well as maintaining the performance during storage, etc.

The chemical characterisation of the leachable profile of medical devices plays an important role due to the relationship that exists between the profile of extractable substances and the biocompatibility of the device, both locally and systemically.

The relationship will be taken into consideration in the upcoming examination of the biocompatibility according to Standard PN-EN ISO 10993-1:2010, and in the investigation concerning the impact of storage conditions on the changes in leachable profiles of selected prototypes of textile implants.

The investigations carried out showed that the evaluation of the profile of extractable substances is an indication of chemical purity of the textile medical devices which differ in composition, structure, processing procedures and also in the nature and time of contact with the patient's body. Equally important is the evaluation of structural and topographical properties of the medical devices. Taken together, the broad testing shall exhaustively characterise the impact of all of the quality parameters on the biological response to the implanted textile device.

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References

1. Górecki R. Treatment of urinary incontinence. Current state and directions of development (in Polish). *Przegląd Urologiczny* 2006; 7/2: 36.
2. *Incontinence: causes, management and provision of services*, Royal College of Physicians of London, 1995.
3. Jolleys JV. *Incontinence.* Royal College of General Practitioners London, 1994.
4. Cody J, et al. *Systematic review of the clinical effectiveness and cost-effectiveness of tension-free vaginal tape (TVT) for treatment of urinary stress incontinence.* Report commissioned by NHS R&D HTA, Programme on behalf of the national Institute for Clinical Excellence 2002, http://www.hta.ac.uk/pdfexecs/summ721.pdf [2011-12-10].
5. Struszczyk MH, Olejnik M. Present and future demand for textile medical devices (in Polish). *Techniczne Wyroby Włókiennicze* 2010; 18, 3/4: 19-25.
6. Baranowski W. Implant as a lift. *Żyjmy Dłużej* 2007; 11: 18-19.
7. Anton F. et al. The phenomenon of infection with abdominal wall reconstruction. *Biomaterials* 2007; 28: 2314-2327.
8. Klosterhalfen B., et al. The lightweight and large porous mesh concept for hernia repair. *Expert Rev. Devices* 2005; 2(1): 1-15.
9. Welty G., et al. Functional impairment and complaints following incisional hernia repair with different polypropylene meshes. *Hernia* 2001; 5: 142-147.
10. Struszczyk MH, Gutowska A, Kowalski K, Kopias K, Pałys B, Komisarczyk A, Krucińska I. Ultra-light knitted structures for application in urologynaecology and general surgery – Optimisation of structure in the aspect of physical parameters. *Fibres & Textiles in Eastern Europe* 2011; 19, 5(8): 92-98.
11. Wintermantel E., Mayer J. Anisotropic biomaterials strategies and developments for bone implants. In: Wise DL, Trantola DJ, Actobelli DE, Yaszeniski JD, Gresser JD, Schwarz ER (eds) *Encyclopaedic Handbook of Biomaterials and Bioenerineering, Prat-B* New York, Marcel Dekker, 1995, 3-42.
12. PN-EN ISO 14155:2011: Clinical investigation of medical devices for human subjects - Good clinical practice (in Polish).
13. PN-EN ISO 14155:2011: Clinical investigation of medical devices for human subjects - Clinical investigation plans (in Polish).
14. PN-EN ISO 10993-18:2009: Biological evaluation of medical devices - Part 18: Chemical characterization of materials (in Polish).
15. PN-EN ISO 10993-12:2009: Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (in Polish).
16. PN-EN ISO 14630:2009: Non-active surgical implants. General requirements (in Polish).
17. Struszczyk MH, Kopias K, Kowalski K, Golczyk A. Trójwymiarowy, dziany implant do rekonstrukcji ubytków tkanki łącznej. PL P-394623, 2011.
18. Struszczyk MH. Introduction of chitin and its derivatives for the design of medical devices based on the requirements of EU Derivative 93/42/EWG. In: Senel S, Varum KM, Sumnu M, Hinncal A (eds) *Proceedings of the 8th International Conference of the European Chitin Society.* ISBN 978-975-491-250-0, 2007, 186-192.
19. Struszczyk MH, Rogaczewska A, Dobrowolska A, Majcherek Z. The elaboration of optimal structure of flat implants for hernia treatments. *Fibres & Textiles in Eastern Europe* 2009; 17, 1(72), 103-110.
20. *Laboratory of Paper Quality of Institute of Biopolymers and Chemical Fibres*.
21. Struszczyk MH, Kowalski K, Kopias K, Komisarczyk A. Aspects of the risk analysis in designing of textile medical devices for use in urogynaecology and general surgeries. In: *Proceedings of IXth International Conference Knitt Tech 2010*, Rydzyna/Poland, 17 - 19.06.2010.
22. Struszczyk MH, Komisarczyk A, Krucinska I, Kowalski K, Kopias K. Ultra-light knitted structures for application in urologynaecology and general surgery – optimisation of structure. In: Talvenmaa P (ed) *FiberMed11 Proceedings*, ISBN 978-952-15-2607-15-2607-7, 2011.

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