AUTEX Research Journal, DOI: 10.1515/aut-2018-0016 © AUTEX

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THE ANALYSIS OF STRUCTURE AND PHYSICOCHEMICAL PROPERTIES OF YARNS USED FOR MANUFACTURING HERNIA MESHES

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Abstract:

The article presents a comparative analysis of the yarns used for manufacturing hernia meshes. For the analysis, two different linear masses, 46 dtex and 72 dtex, of transparent and dyed yarns were used; the dye used in the yarns was adequate for their intended use. The DSC tests showed the influence of thermal treatment on the change of thermal properties of the yarns. At the same time, it was proved that the aforementioned treatment had a bearing on the changes of crystallinity degree. All types of yarns were also subjected to physicochemical tests required for all the materials used for the production of hernia meshes.

Keywords:

yarn, hernia mesh, polypropylene, DSC, crystallinity degree

Introduction

The incidence of different types of hernias is one of the major problems diagnosed in modern patients. In this condition, a surgical procedure is required. Its aim is to introduce a biomaterial/limiting implant, eliminating the pathological delamination or rupture of muscles. At present, these types of surgeries constitute approximately 2–9% of all the surgical procedures.[1] The advancement of medicine contributed to the development of new treatment methods of these pathologies and the use of different material structures. Among hernia treatment methods, the most important are the ones that are tension-free and laparoscopic.[2] The most common polymers used for the manufacturing yarns used for the production of meshes are polypropylene (PP), polytetrafluoroethylene (PTFE) or polyesters (PTE).[3] However, at present, the most important polymer for the production of hernia meshes is polypropylene. [4-7] Its history of use in this application dates back to 1960's[8] – to the first generation of biomaterials. Polypropylene is a non-degradable polymer that is widely used in the manufacturing of implants intended for long-term use with no need for reoperation. As a material inert for natural tissues, it is the main polymer used for manufacturing hernia meshes all around the world. What is also important, polypropylene is easy to process into a fibrous form and a wide range of yarns can be obtained from it. For the production of hernia meshes, it is possible to use both monofilament and multifilament yarns.[9] However, in a majority of polypropylene hernia meshes, a monofilament yarn is used that assures obtaining high porosity of the implant, easy overgrowth of capillaries and reduction of risk of infection.[10,11] An important factor is also the possibility of forming appropriate knitting weaves ensuring adequate performance parameters.[12-14] Apart from the issues related to applying appropriate knitting weaves, many research centers carry out studies on modelling the surface properties of the meshes by adding different finishing treatments or using mixed yarns containing biodegradable polymers or bioactive agents.[15-19] Nevertheless, the most important aspect from the point of view of manufacturing implantable materials is using for production the substrates that have well characterized structure and properties. All this has, as a consequence, limited the post-implantation complications risk.

The aim of this article is to carry out a complex physicochemical analysis of the yarns used for the production of meshes used for surgical treatments of hernias. Getting to know both structure and properties of the yarns will enable to determinate the technological regime of manufacturing implantable raw materials used for supporting connective tissue in hernias, especially the abdominal ones. By understanding the yarns' properties, especially their behavior during thermal treatment, it will be possible to eliminate the negative operations causing the yarns to lose their functional properties.

Materials and test methods

Used Material – The materials used for the investigations were monofilament transparent and blue polypropylene yarns manufactured by Monosuisse (linear mass of both yarns was 46 dtex and 72 dtex) were subject to tests. The yarns underwent thermal treatment at temperature of 140°C, 150°C, 155°C and 160°C.

Mechanical properties – the breaking force for the yarn was determined on Instron testing machine in conditions complying with PN-EN ISO 13934-1 norm.

Thermal properties and crystallinity degree of the yarns – were determined on the basis of the tests involving differential scanning calorimetry (DSC) for 3 cycles: I – heating – from

-80°C to 200°C at the rate of 10°C/min; II – cooling from 180°C to -80°C at the rate of 20°C/min; III – heating from –80°C to 200°C at the rate of 10°C/min. The obtained data were used for establishing the enthalpy value for crystalline phase and on its basis, the crystallinity degree was determined.

Yarns' chemical structure tests – determined on the basis of infra-red FTIR tests with the use of ATR module. The tests were carried out at wavelengths between 4000 cm^{-1} to 400 cm^{-1} and the resolution of 4cm^{-1}.

Physicochemical tests of water extracts – the aim of the tests was to show the safety of use of blue pigment as a coloring additive. The yarn after the cleaning treatment removing the preparation in an autoclave (121°C, 60 min.) and after the thermal treatment (155°C, 90 sec.) was subjected to tests. From the test material, water extracts were obtained in acc. with PN-P-04894 norm (at a temperature of 121°C during 60 min.), which were later subjected to chemical tests that included the pH of the extract as in PN-EN ISO 3071, and permanganate oxidability as in PN-P-04896[1] – this method is based on determining the amount of $KMnO_4$ solution used for reaction with organic and non-organic substances eluted from the medical device. Also, the following tests were carried out: maximum absorbance in ultraviolet at a wavelength between 230–800 nm as in PN-P-04990[1], chloride ion content (Cl^-), sulphate ion content (SO_4^{2-}), ammonia ion content (NH_4^+), and heavy metals content (Pb^{2+}). Moreover, the tests of frothing agents content as in PN-P-04781-14[1], non-fibrous substances content and electrical conductivity were carried out.

Pigment release – determined with the use of UV-VIS Jasco V670 spectrophotometer. The test consisted in measuring the changes of intensity of monochromatic light passing through the tested sample/solution placed in a testing vessel.

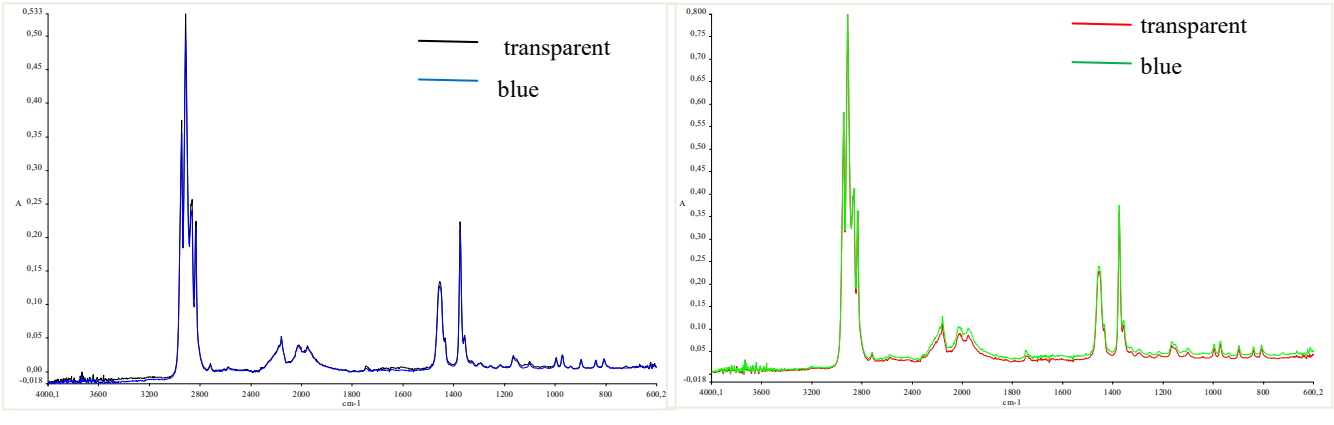
Test results and discussion

Yarns' chemical structure tests

The conducted FTIR tests clearly prove that all types of yarns were manufactured out of the same raw material – polypropylene. The chemical structure determined with the use of FTIR tests is exactly the same for all the yarns, regardless of their color. However, in the obtained FTIR spectra, it is impossible to extract the characteristic vibrations of bands of chemical bonds originating from the pigment (Fig. 1). The FTIR spectra are characterized by almost identical height of bands proceeding from the vibrations of $-CH_3$, $-CH_2$ and -CH bonds at the range of 3000–2700 cm^{-1}. It shows that the share of the aforementioned groups is the same in the compared yarns.

Thermal properties and crystallinity degree of the yarns

The DSC curves presented below (Fig. 2) indicate the influence of thermal treatment on changes in the melting process of crystalline areas present in the yarns. It is particularly visible during the thermal treatment at 140 and 150°C. It these cases, a double peak during melting process is visible, both in transparent and colored yarns. It is difficult to explain why the same phenomenon was not observed in the case of thermal treatment at a higher temperature. Taking into consideration the analysis of crystallinity degree of all the yarns, it can be stated that thermal processing does have an influence on it. Table 1 presents the obtained crystallinity degree values for both raw yarn (not subjected to thermal treatment) and for yarns that underwent the thermal treatment. For transparent 46 dtex yarn, the increase of treatment temperature causes a systematic increase of crystallinity degree and its biggest share can be observed at a temperature of 160°C. For blue 46 dtex yarn, the highest crystallinity degree values were obtained at 155°C. In this range, the crystallinity degree is the highest and amounts to 55%. In comparison to the yarn of the same diameter but without the addition of pigment, the share of crystalline phase is higher at a temperature of 155°C (52%–55%). The transparent 72 dtex yarn reaches the highest proportion of crystalline phase when processed at 140°C (52%). Any further treatment decreases the share of this phase. The addition of pigment into the 72 dtex yarn leads to an increase of the crystalline phase share and its highest proportion can be observed while processing at 155°C (54%). The first cycle shows the history of processing of the polymer. For yarns with addition of pigment (batch dyeing), the crystallinity degree will be higher, owing to a preferential heterogeneous nucleation. The smaller diameter of the yarn, in the case of the transparent 46 dtex one, will cause



A) B)

Fig 1. FTIR ATR spectra of PP fibers of the following linear mass: A) 46 dtex transparent and blue; B) 72 dtex transparent and blue

a quicker heat transfer when forming fibers via spinneret; it will be responsible for creating a higher proportion of amorphous or mesomorphic phase – which explains lowered crystallinity degree.

Mechanical properties tests

The correlation between the applied thermal treatment temperature and the changes in mechanical properties was tested on the basis of breaking force parameters (Fig. 3).

Thermal processing of 46 dtex transparent yarn causes a systematic decrease of mean values of breaking force and an increase of the scope of error. The highest strength parameters can be found in the raw yarn and in the yarn processed at 140°C. On the other hand, the yarn processed at 160°C is characterized by the lowest breaking force. In the case of yarn with the addition of pigment, the lowest breaking force possesses the yarn processed at 155°C – blue yarn processed at 160°C melted down. Raw yarn and the yarn processed at 140°C are characterized by the best parameters.

The thermal treatment has a significant impact on the change of breaking force parameters for 72 dtex transparent yarn – it causes their systematic decrease. The yarn processed at 155°C has the lowest mean breaking force. On the contrary, the highest rate of this parameter can be observed in raw yarn. The addition of pigment causes the established mean breaking force to decrease systematically when the processing temperature increases. Table 2 presents the comparison of significant differences between the obtained values of breaking force.

The analysis of significance of differences in the test results depending on the processing (Table 2) enabled the following observations: regardless of the yarn diameter and its color, processing at a temperature of 140°C did not influence the breaking force of raw yarns. For each yarn, the measurement areas overlap. The processing at 150°C significantly changes this parameter only for the yarns with the addition of pigment (blue) – in comparison with rest of the test results. The treatment at 160°C caused a significant change of strength parameters in raw yarns. In turn, in the case of thermal treatment at 155°C,

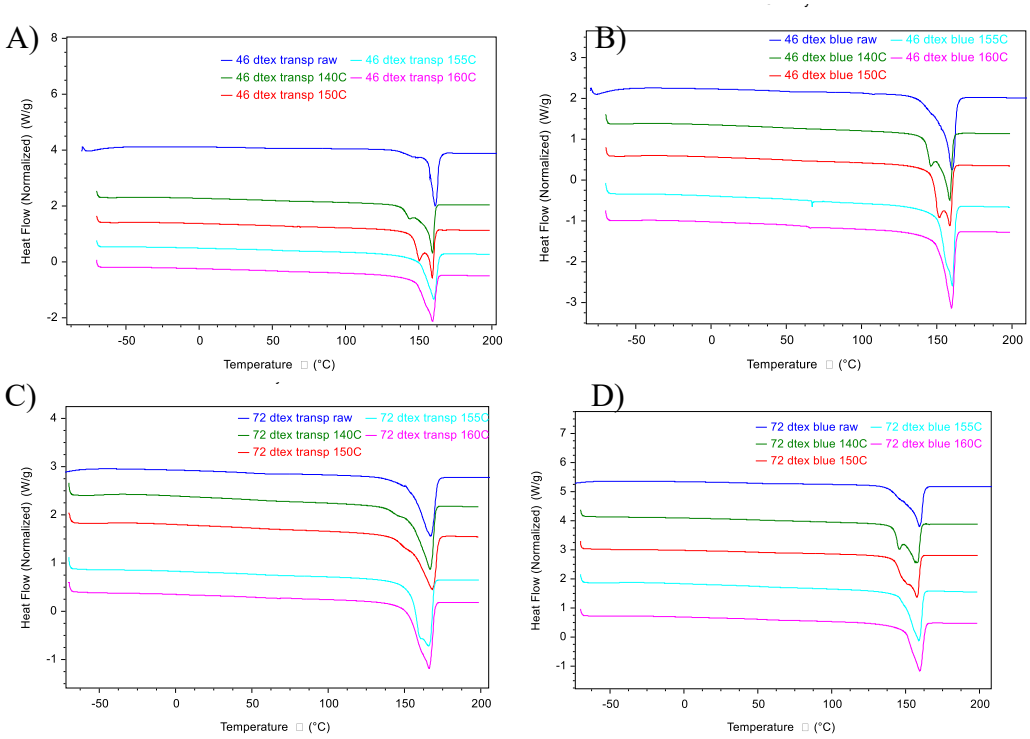


Fig 2. Comparison of DSC curves for: A) 46 dtex transparent yarn, B) 46 dtex blue yarn, C) 72 dtex transparent yarn, D) 72 dtex blue yarn

Table 1. Crystallinity degree for yarns of different linear masses which underwent thermal treatment in the same conditions

Linear mass	46 dtex		72 dtex	
Yarn color	transparent	blue	Transparent	blue
Raw	42.4	60.4	49.5	50.6
140	47.7	51.6	52.3	50.1
150	49.5	53.0	47.3	50.6
155	51.9	51.5	51.1	51.3
160	52.4	55.3	48.3	53.8

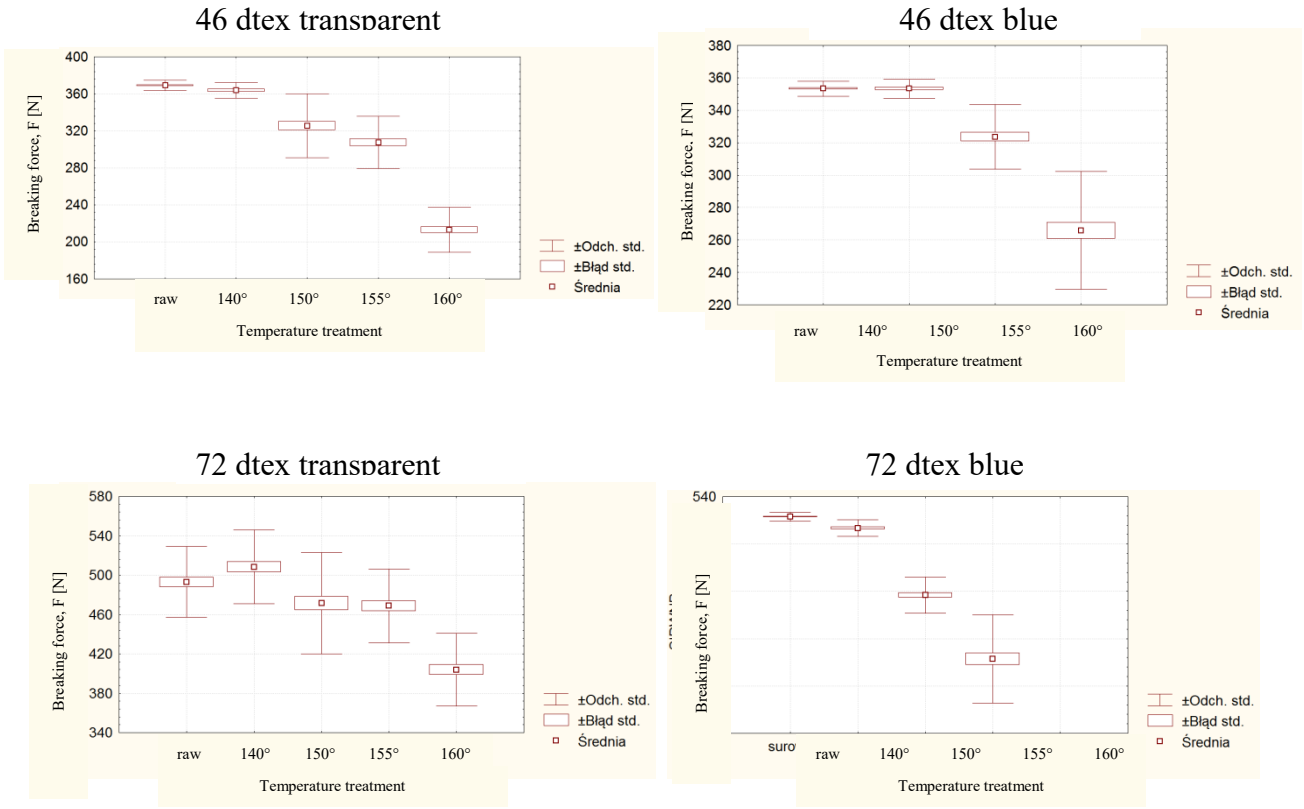


Fig 3. Tests of breaking force depending on thermal treatment temperature for all yarn types

Table 2. Comparison of significant differences between mechanical resistance to breaking for each tested yarn, depending on processing temperature

Breaking force	**Raw**		**140°C**		**150°C**		**155°C**		**160°C**	
	transp	**blue**	**transp**	**blue**	**transp**	**blue**	**transp**	**blue**	**transp**	**blue**
raw	**X**		**46, 72**	**46 b 72b**	**46, 72**	**46b 72b**	**46, 72**	**46b 72b**	**46, 72**	
140°C	46, 72	46b 72b	**X**		46, 72	46b 72b	46, 72	46b 72b	46, 72	
150°C	46, 72	46b 72b	46, 72	46b 72b	**X**		46, 72	46b 72b	46, 72	
155°C	46, 72	46b 72b	46, 72	46b 72b	46, 72	46b 72b	**X**		46, 72	
160°C	46, 72,		46, 72		46, 72		46, 72		**X**	

only 46 dtex yarn presents a significant change in the breaking force value.

The yarns with the addition of dye are more sensitive to higher temperatures, which was observed on the basis of a significant change of mechanical parameters already in processing at a temperature of 150°C – in comparison with raw yarns and yarns processed at 140°C. The yarns without the addition of pigment are less prone to changes of mechanical parameters after processing at higher temperatures.

At the same time, no correlation between the crystallinity degree and the obtained values of breaking force for a given yarn was observed. For each analyzed sample, the significance level p was higher than 5% ($p > 0.05$), which means that the correlation coefficient is not significantly different from 0. The established Pearson correlation coefficients were the highest for blue 72 dtex yarn and it was equal to 0.84, which means that the correlation is almost a linear one; the determination coefficient showed that the change of crystallinity degree and breaking force were correlated in 71%.

The analysis of correlation between thermal treatment temperature and crystallinity degree showed that in the case of 46 dtex yarn, both transparent and blue, there is a strong correlation; the significance level was less than 5% ($p < 0.05$), which means that the correlation coefficient is significantly different from 0. The established Pearson correlation coefficients were equal to 0.93 and 0.98; the determination coefficient indicated that the change of crystallinity degree in 86% and 96%, respectively, depended on processing temperature.

Chemical tests

Chemical analyses applied as standard in chemical purity tests of knitted products intended for medical use, as shown by TRICOMED SA experiences, indicate maximum values above which a material should not be used for manufacturing medical devices. The required ranges and test results are presented in Table 3. So far, the experience of TRICOMED SA shows that chemical purity of polypropylene yarns is the same within a given color (transparent and blue), regardless of their diameter. This is the reason why the 46 dtex yarn was chosen for the tests. Chemical purity should be tested after the cleaning treatment, for example, in tumbler washers (30-40°C) or autoclaves (121°C). It is related to the fact that surface preparations, which are surfactants, significantly disturb the results of chemical purity tests.

The chemical tests compared the water extracts of 46 dtex blue and transparent yarn, before and after the cleaning treatment. The pH tests show that the extract from yarn with preparation on its surface (raw yarn) is characterized by a more acid pH in comparison with cleaned yarn. The pH values of transparent yarn differ statistically between themselves and their values are the most disparate – the raw yarn = 6.4 and the cleaned one = 7.8. In the case of blue yarn, the water extract of raw yarn also presents a higher pH value in comparison to the cleaned product – 7.1 and 7.5, respectively. However, the obtained results are not statistically different. The pH of distilled water was equal to 8.17. The pH value test results should be below this level, but also should not exceed the minimal pH value = 5.5. The test results of both raw and cleaned yarns were within the required range. The permanganate oxidability tests aim at determining the chemical substances (easily oxidable residues of organic and non-organic compounds) contained in the water extracts of a given testing materials, which are oxidized by MnO_4^- in an acid environment.

The cleanliness and purity requirements for medical devices made from polypropylene yarns cannot exceed 0.12 mg O_2/g. The test results for raw yarns are between 0.25 O_2/g to 0.32 O_2/g, which means that the amount of preparation on the yarn's surface is significant. However, the yarns after cleaning treatment are characterized by much lower results as compared with the norms; for the blue yarn, it is 0.003 O_2/g, and for the transparent one, 0.012 O_2/g. Such results prove the effectiveness of the cleaning treatment. What is more, it can be concluded that no organic or non-organic chemical substances raising the degree of chemical oxidation are released from the yarn. In terms of UV radiation, two electromagnetic wavelengths were determined (230 nm and 245 nm), for which, in accordance with TRICOMED's experience, it is possible to establish the degree of absorbance with the greatest possibility – this parameter determines the microbiological purity. The maximum permissible value of absorbance is 3.0. The mean value for the tests of raw blue yarn at a wavelength of 230 nm exceeds the maximum value (0.322). For a wavelength of 245 mn, the mean result fits within the acceptable value (0.119). The absorbance test results at wavelengths of 230 mn and 245 mn for blue cleaned yarns are much below the maximum value (0.028 and 0.0137, respectively). The average absorbance values of water extracts of raw and cleaned transparent yarns together with the error range are within the maximum permissible value for both tested wavelengths – 230 nm and 245 nm. Despite proving much lower absorbance value than permissible, there is a statistically significant difference between the results of raw and cleaned yarn. The water extract of the processed yarn is characterized by 10 times higher purity than the extract from raw yarn. However, there is no significant difference between the extracts of cleaned blue and transparent yarns. For both yarns, the absorbance at both wavelengths, 230 nm and 245 nm, is below 0.03.

The results of electrical conductivity in water for raw yarns are much higher than the results obtained for the same yarns that were subjected to cleaning treatment prior to the tests: raw yarn – transparent 4.4 μS, blue 6.2 μS; cleaned yarn – transparent 0.95 μS, blue 1.15 μS. In the test results for raw yarns, there is a statistically significant difference – the conductivity is higher for blue yarn. Water extracts of cleaned yarns do not differ between themselves in a statistically significant manner.

The tests of frothing agents content show that the preparation on the surface of the yarn causes a significant frothing of raw yarns' water extract. The extract did not show any signs of frothing in the case of cleaned yarns, which means that cleaning treatment in an autoclave is an efficient and repeatable way of cleaning the yarn surface from surfactants for both transparent and blue yarns. The tests of non-fibrous substances content (substances soluble in light petroleum) were carried out in order to qualitatively determine the amount of preparation residues on the yarn after the thermal and cleaning treatment. The obtained test results show that the residues of non-fibrous substances were significantly lowered after the cleaning treatment. In accordance with the data provided by the manufacturer of the yarn, the preparation content may reach a maximum of 0.18±0.06% of yarns' mass. The amounts determined during the tests are higher, which means that apart from preparation, on the surface of the yarn other contamination can be present (e.g., dust) or the residues of ether that had not vaporized completely.

Pigment release into the water extract

Raw transparent and blue yarns were tested for absorbance of characteristic wavelengths (Fig. 4).

The tests carried out with the use of spectrophotometer show that characteristic wavelengths for yarns with the addition of pigment are: 595 nm and 693 nm. For transparent yarns at a visible range, the peak was observed for a wavelength of 693

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Table 3. Chemical test results for 46 dtex transparent and blue yarns, both raw and after cleaning treatment

No.	Tested parameter		Unit	Requirements	Raw yarn		Yarn after cleaning treatment		Test method
				46 dtex transparent	46 dtex blue	46 dtex transparent	46 dtex blue		
2.	pH of the sample		pH unit	5.5 ÷ 8.0	6.4 ± 0.1	7.1 ± 0.2	7.8 ± 0.3	7.5 ± 0.4	PN-EN ISO 3071
3.	Permanganate oxidability		mg O_2 /g	max. 0.12	0.324 ± 0.006	0.254 ± 0.08	0.012 ± 0.003	0.003 ± 0.001	PN-P-04896
4.	Max. absorbance at a range of characteristic wavelength		-	-	693 nm	595 nm 693 nm	not demonstrated	not demonstrated	-
5.	Max. UV absorbance at a wavelength	230 nm	-	max. 0.3	0.180 ± 0.012	0.322 ± 0.059	0.0280 ± 0.0104	0.0260 ± 0.0004	PN-P-04990
		245 nm			0.119 ± 0.005	0.230 ± 0.044	0.0137 ± 0.0021	0.0078 ± 0.0028	
6.	Frothing agents		Froth height (cm)	none	0.75 ± 0.07	0.9 ± 0.3	none	None	PN-P-04781-14
7.	Non-fibrous substances content		%	1	0.42 ± 0.03	0.48 ± 0.01	0.17 ± 0.07	0.29 ± 0.11	PN-P-04607
8.	Electrical conductivity		µS		4.4 ± 0.4	6.2 ± 1.1	0.95 ± 0.21	1.15 ± 0.07	PN-EN 27888
9.	Chloride ions content		mg Cl^-/g of the sample	< 0.02	< 0.02	< 0.02	< 0.02	< 0.02	PN-P-04895
10.	Ammonia ions content		mg NH_4^+/g of the sample	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	PN-P-04992
11.	Sulphate ions content		mg SO_4^{2-}/g of the sample	< 0.05	< 0.05	< 0.05	< 0.05	< 0.05	PN-P-04781
12.	Heavy metals ion content		mg Pb^{2+}/g of the sample	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	PN-P-04991

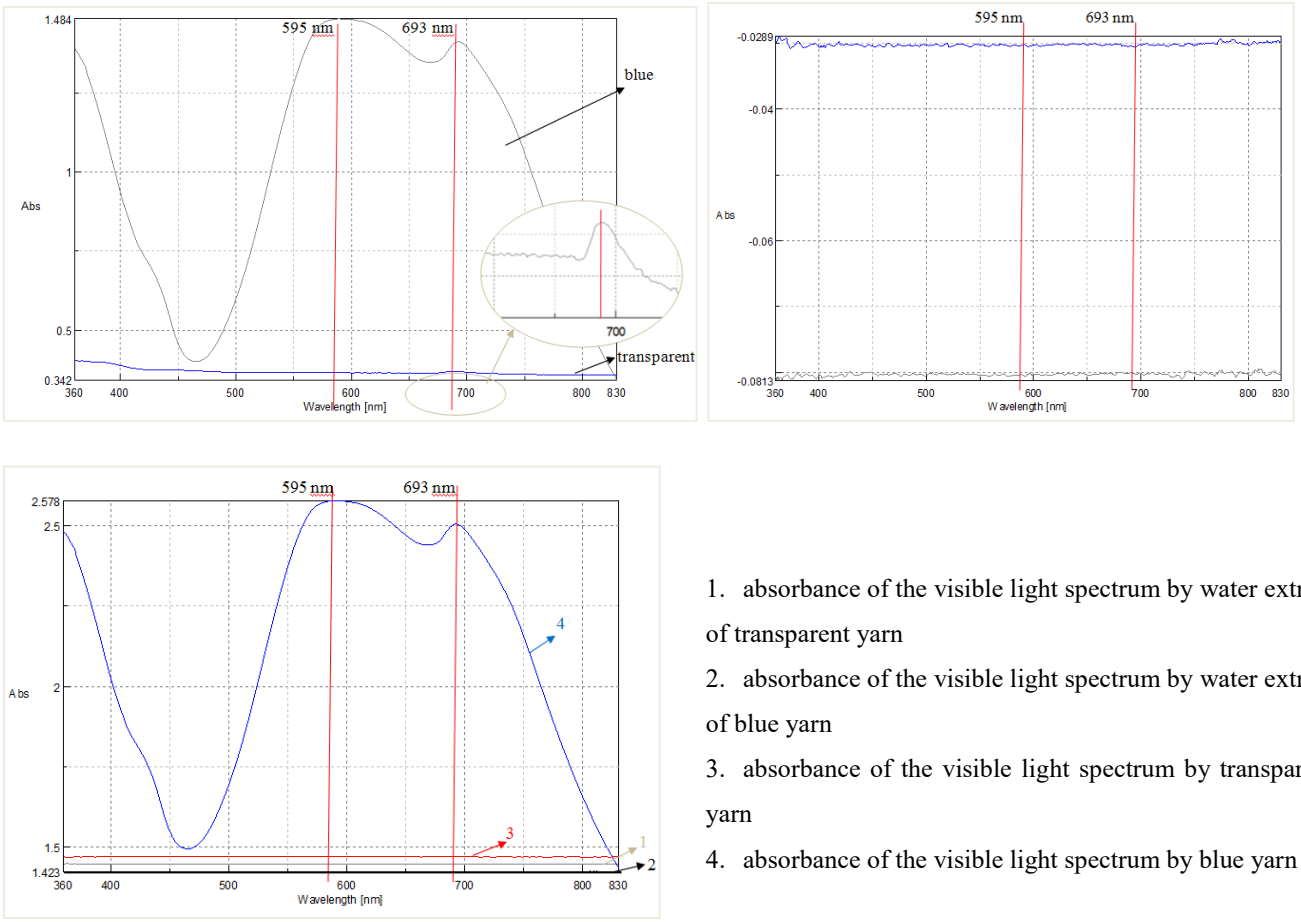

Fig 4. Presentation of test results of electromagnetic radiation absorbance at a visible range 400-830 nm; a. presentation of test results for blue yarn ( ) and transparent yarn ( )

nm. It means that the characteristic absorbance value (A) for polypropylene is 693 nm, and for the pigment, it equals 595 nm.

If compounds present in the tested yarn were released into the extract, such action would be visible in the absorbance runs. The established absorbance runs for water extracts show that for both transparent and blue yarns, the characteristic wavelengths were not determined. For the tested water extracts, there was no energy absorbance either at a wavelength of 595 nm or at 693 nm. It shows that no pigment compounds that would be able to absorb the determined wavelengths were released to the extract in the case of tested yarns.

Summary

The conducted comparative analysis of polypropylene yarns (transparent and blue ones) showed no differences visible in the FTIR spectra in their chemical composition. For all types of yarns, the same peaks of characteristic vibrations of chemical bond bands and similar absorbance rates were obtained. The DSC analysis proves that the introduction of a preliminary thermal treatment results in the change of the character of the crystalline areas melting process. For the thermal processing at 140 and 150°C, a double crystallinity peak is visible, which cannot be seen in the case of other processing temperatures. At the same time, in all tested yarns, the influence of thermal treatment on the obtained values of crystallinity degree and breaking force can be detected. The analysis of chemical properties showed that all yarns contain preparations, which have to be removed from the finished product so that the product itself can be used for medical applications. The yarns with the addition of pigment underwent the tests of pigment release into the water extracts; the tests proved that this phenomenon does not take place in the case of the tested yarns. All the results indicate that the tested yarns are safe for manufacturing hernia meshes.

ACKNOWLEDGEMENT

The manuscript was partially financed from funds assigned for 14-148-1-2137 statuary activity by Lodz University of Technology, Department of Material and Commodity Sciences and Textile Metrology, Poland

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