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The influence of X-rays on strength properties of polyester vascular system prosthesis

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Properties

ABSTRACT

Purpose: of this paper was to evaluate the influence of X-ray irradiation on mechanical properties of polyester yarn used in production of vascular system prosthesis. Patients with such prosthesis are subjected to multiple X-ray radioscopic exposures. This can negatively influence prosthesis strength and durability.

Design/methodology/approach: Polyester yarn tensile strength properties were measured before sterilisation and X-ray irradiation. Next a part of yarn was subjected to irradiation sterilisation. Sterilised and non-sterilised yarn was next exposed to multiple X-ray irradiation and to continuous irradiation. After each irradiation dose tensile strength and elongation at break were measured.

Findings: The influence of X-ray irradiation dose on mechanical properties was evaluated. It was established that dose equivalent to multiple X-ray radioscopic exposures did not substantially influenced strength properties of polyester yarn.

Research limitations/implications: To fully evaluate the influence of X-ray irradiation on prosthesis strength and durability working in human body environment it is planned to continue described research. Simultaneous influence of X-ray irradiation and body fluids on mechanical properties of polyester yarn will be tested.

Practical implications: Research results proved that patients with polyester vascular prosthesis may be subjected to X-ray radioscopy without any anxiety concerning prosthesis strength properties or durability.

Originality/value: The main research value is its basic conclusion that multiple X-ray irradiation does not significantly influence strength and flexibility of polyester yarn applied to vascular system prosthesis manufacture.

Keywords: Mechanical properties; Polyester biomaterials; X-ray irradiation

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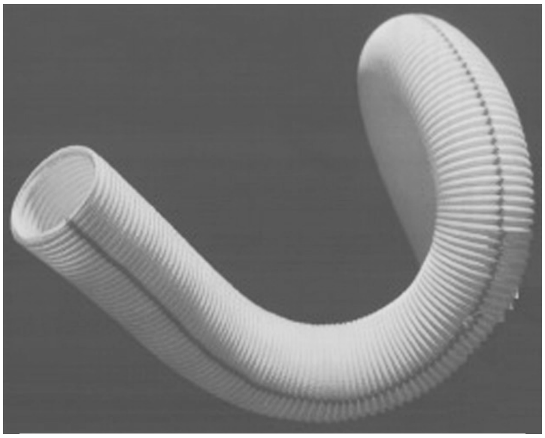
1. Introduction

For nearly half a century synthetic, polymeric vascular grafts have been intensively used in vascular system surgery. However, while large inner diameter prostheses are widely accepted, especially in aortic and iliac surgery, smaller diameter prostheses cause many problems. They are intensively searched in recent years because of their limitations. The main reasons for poor performance of small-diameter (less than 4 mm) to medium-diameter (up to 7 mm) grafts are anastomotic intimal hyperplasia and ongoing surface thrombogenicity [1]. In spite of these drawbacks and problems of contemporary vascular prostheses, no alternative solution has yet found that enables to replace the most current synthetic grafts in near future. Even though sophisticated tissue engineering solutions were proposed [2-5] the majority of surgeons continue to apply the well-established products known from decades. Also commercial grafts are still produced on the basis of material choices, mechanical properties, surgical preferences rather than taking into account biological integration and functional tissue regeneration. On the other hand, regenerative medicine has made significant progress in recent years and it is only a matter of time until synthetic vascular prostheses will also benefit from this development [1].



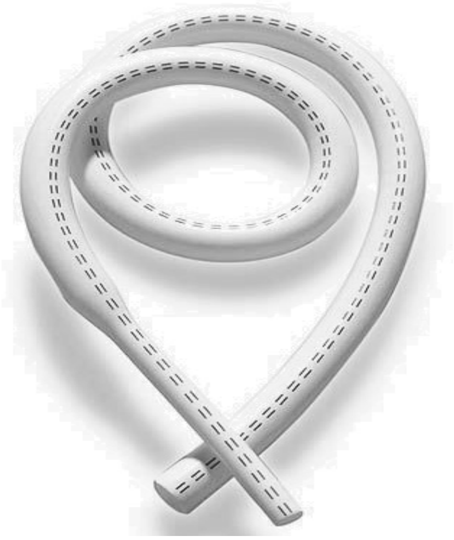
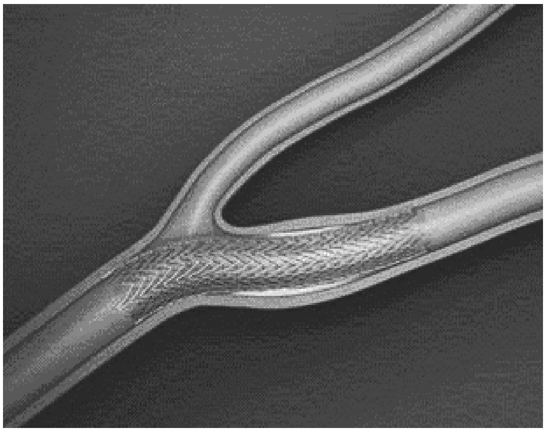


Fig. 1. Vascular system (blood vessel) prostheses manufactured from polyester yarn [15,16]

Synthetic yarns are more and more frequently applied in vascular system therapy. Most often they are used as different type of textiles to manufacture vascular system prosthesis. Woven and knitted cardiovascular prostheses are tubular structures made mainly of polyester filaments.

The conditions of use require particular mechanical properties of the material, such as elasticity, tensile and bending strength because of pressure and pulsatile blood flow [6]. To enhance performance in human body characteristics many modifications of fibres surface and textile structure are proposed [7-15].Also water permeability, burst resistance, deformation resistance, and suture retention are very important [12].

Among others they are used as bypasses to derive blood circulation or to replace failed blood vessels (Figs.1 and 2) [6-10]. Apart from polyester, polyamide, polyurethane and poly(tetra-fluoro-ethylene) (PTFE) are used in this field [9,10,11]. Poly(tetra fluoro-ethylene) is used in two basic structures: nodes and fibrils.



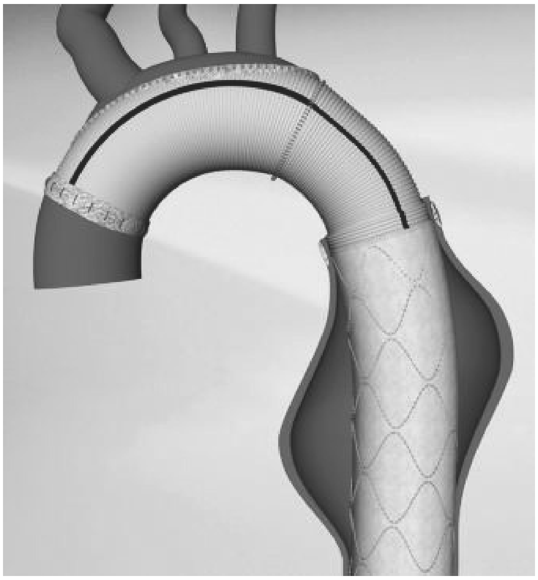


Fig. 2. An example of vascular system prosthesis applications [17,18]

Polyester (poly ethylene terephtalate – PET) prostheses consist of one basic elementary form, namely fibers. Fibers are mostly bundled into multifilament yarns that are either woven or knitted into a fabric (Figs. 3,4,5) [19]. Consequently there are in two different structures determining the shape and the dimensions of voids. Weaving gives narrow spaces for tissue ingrowth and knitting leads to looser patterns containing larger voids and more space for tissue ingrowth. Woven material is preferred by surgeons, because it provides high bursting strengths, low permeability to liquids and minimal tendency to deform under stresses. The almost complete impermeability of woven PET is opposed by a range of limited ingrowth spaces in knitted PET.

Tissue ingrowth is very limited in woven polyester grafts, seldom penetrating the entire wall thickness. Even if it extends to the inner capsule, it hardly manages to break through the compacted fibrin to reach the blood surface, even after many years of implantation [1].

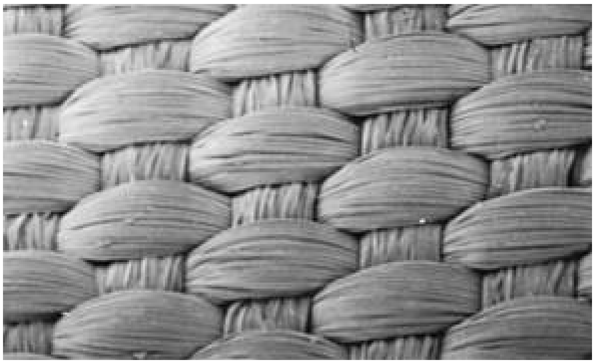


Fig. 3. Close-up photograph (×50) of a woven polyester prosthetic vascular graft [19]

Fig. 4. Close-up photograph (×50) of a knitted polyester prosthetic vascular graft [19]

The porosity of knitted and to some extent even woven polyester prostheses eventually allows a certain degree of tissue ingrowth from outside. At the same time, however, it seems again that the compacted inner fibrin capsule on the blood surface of polyester grafts represents an ingrowth barrier for transmural connective tissue regardless of whether the grafts are knitted or woven [1].

Fig. 5. Photograph (×50) of the external surface of a woven double velour polyester graft [19]

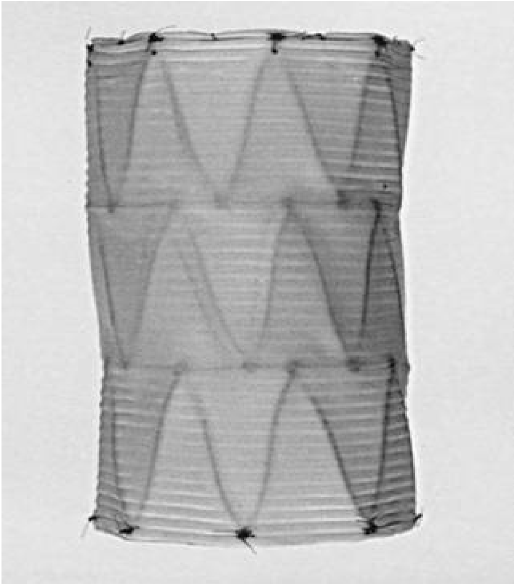


Fig. 6. A polyester graft is mounted on an expandable metallic stent [19]

Polyester yarns are also applied together with expandable metallic stents (Fig. 6) [19].

Additional and interesting problem is that patients living with vascular system prostheses may be periodically subjected to X-ray radioscopic exposures. High energy irradiation is also active in environment in many different irradiation kinds, such as cosmic radiation, gamma radiation or radon and radioactive wastes radiation. X-ray doses are expected to influence negatively prosthesis strength and durability. High energy X-ray irradiation is one of known sources of polymeric materials ageing and in this way degradation.

X-rays are very high energy with capable to destroy many of chemical bonds present in polymers structure. They are divided into smaller energy 'soft X-rays' and higher energy 'hard X-rays (γ-rays)'. Radioscopic exposures include mainly soft X-rays, which are called in brief 'X-rays' in contradiction to 'γ-rays'. Many methods have been developed to measure the energy dissipated in various media by high energy radiation. The exposure dose is usually given in roentgens, rad or greys. The grey [Gy=1J/1kg] is official SI unit of radiation dose

Biological effect of irradiation depends not only on energy of dose absorbed by human body but also on the type of irradiation. Because of this an equivalent dose was introduced. The unit of equivalent dose is 1 sievert (Sv). The equivalent dose to a tissue is found by multiplying the absorbed dose, in grays, by a dimensionless "quality factor" Q, dependent upon irradiation type, and by another dimensionless factor N, dependent on all other pertinent factors. N depends upon the part of the body irradiated, the time and volume over which the dose was spread, even the species of the subject. Together, Q and N constitute the irradiation weighting factor, W_R .For an organism composed of multiple tissue types a weighted sum or integral is often used [20]. Although the sievert has the same dimensions as the gray (i.e. joules per kilogram), it measures a different quantity.

Typical equivalent doses absorbed by human bodies per year are given in Table 1.

Values given in Table 1 show that X-ray dose absorbed by human body during radioscopic medical examination is important but not the only source of high-energy irradiation.

Allowable dose for human body should not be greater than 5,0 mSv/year. People exhibited to high energy irradiation in their profession the dose should not be greater than 50 mSv/year. Lethal dose for most of people is about 3-5Sv absorbed in one accident.

Table 1.
Typical equivalent doses absorbed by human body in one year time [21]

No	Source of irradiation	Equivalent dose mSv/year
1	Cosmic radiation	0.290
2	Gamma radiation from environment	0.04
3	Radon radiation from environment	0.08
4	Radioactive wastes radiation after nuclear explosion	0.021
5	Radon radiation inside buildings	1.58
6	Roentgen diagnostics	0.78
7	Radiation in mining industry	0.016
8	Gamma radiation inside buildings	0.38
9	Incorporated radionuclides	0.409
10	Other sources	0.005
	Sum	3.601

The main purpose of described here research was to evaluate the influence of X-ray irradiation on mechanical properties of polyester yarn used in production of vascular system prosthesis.

2. High energy degradation of polymers

The radiation chemistry began to attract attention of scientists in fifties years of twenty century when many transformations in polymers structure was observed as a results of high energy irradiation [22,23]. Up till now more and more attention have been paid to the effects of ionizing irradiation and the reactivity of the ions, excited states and free radicals formed.

The main chemical changes induced in polymers by ionizing irradiation are formation and decay of unsaturation, main chain scission, crosslinks formation, volatile products formation, free radicals formation and cyclization. Not all processes are active in all cases. Results depend strongly on chemical structure of polymer and also on environment in which irradiation takes place. The presence of additives in polymer matrix can highly influence the course of irradiation degradation of polymers. Some additives are introduced into polymer matrix to inhibit x-rays effects [22].

X-rays effect also physical properties of irradiated polymers. Irradiation often cause changes in visible and UV absorption spectra of polymers. Discoloration of polymer products is the most visible effect of high energy irradiation. Another effect of X-rays irradiation is electrical conductivity increase. It is very important problem with polymers used in insulating applications. Because X-ray cause also crosslinking, melting temperature increase and crystallinity decrease are frequently observed.

Mechanical properties of most polymers subjected to X-rays are also changed. Generally, mechanical properties deterioration is noticed. The main reason is chain scission and low molecular products formation. Decrease in tensile strength and elongation at break are very often given. Soft and flexible polymers exhibit decrease in the elastic modulus. Due to crosslinking chosen mechanical properties enhancement is also possible. Crosslinking of soft and flexible polymers produces increase in the elastic modulus. In many polymers crosslinking produces increase in tensile strength and elongation at break. Thermoplastic polyesters, used for vascular system prosthesis production undergo mechanical properties deterioration after irradiation and big doses absorption [22]. No extensive research programmes were made to evaluate the influence of various X-rays doses on polyester fibres mechanical properties.

3. Experimental

3.1. Material

Thermoplastic polyester (polyethylene terephtalate - PET) yarn with commercial name 'Torlen' type DTY (84/24 dtex/f) produced by 'Elana' Toruń (Poland) was used in research programme. This yarn is used by many producers of vascular system prostheses. Basic properties of tested fibres, given by the producer, are:

- tensile strength – min 28 cN/tex;
- elongation at break - ~25%;

3.2. Methodology

Polyester yarn subjected to testing was divided into two parts. One part was X-ray irradiated without sterilization and the second part was sterilized before X-ray irradiation. X-rays were applied in 0.5 second impulse unit doses equal 10.35 mGy each. It is approximately equal to basic dose applied in medical diagnostic radioscopy. Additionally part of sterilized yarn was subjected to continuous (10 minutes) X-ray irradiation and afterwards to impulse doses. The dose of continuous irradiation was 126,3 mGy. Total doses applied to tested polyester yarn samples are given in Tables 2 and 3.

Sterilization of yarn was performed using accelerated electrons method.

X-ray irradiation was applied using Roentgen apparatus Siregraph CF produced by Siemens.

Table 2.
Impulse summary doses for sterilized and non-sterilized yarn

No	Number of unit doses	Summary dose mGy
1	10	103.5
2	20	207.0
3	30	310.5
4	40	414.0
5	50	517.5
6	60	621.0
7	70	724.5

Table 3.
Summary doses for continuous and impulse irradiation

No	Number of unit impulse doses	Summary impulse dose mGy	Summary dose mGy
1	0	0	126.3
2	10	103.5	229.8
3	40	414.0	540.3

Polyester yarn was subsequently subjected to tensile test according to PN-P-04654:1984 standard [24]. Tensile test was performed using Zwick tensile tester Textomatic.

Specific tensile strength and elongation at break were evaluated. Specific tensile strength was calculated according to the following equation:

$$R_s = \frac{F}{m} \quad (1)$$

where: F – force at break [cN];
m – linear density [dtex].

Elongation at break was calculated according to equation:

$$\varepsilon = \frac{\Delta l}{l_0} \quad (2)$$

where: l_0 – initial length of sample;
Δl – elongation of sample.

For every measuring point shown in Table 2 and Table 3 thirty tensile tests were performed.

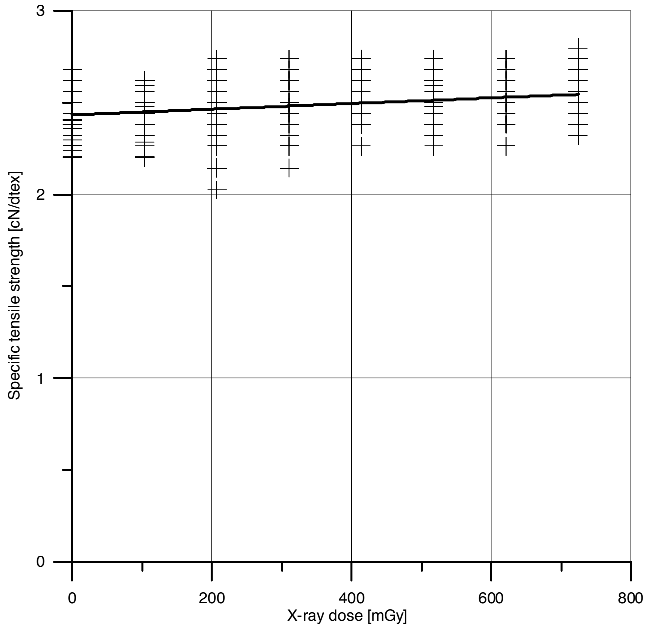


Fig. 7. Dependence of specific tensile strength on X-ray dose for polyester yarn before sterilization

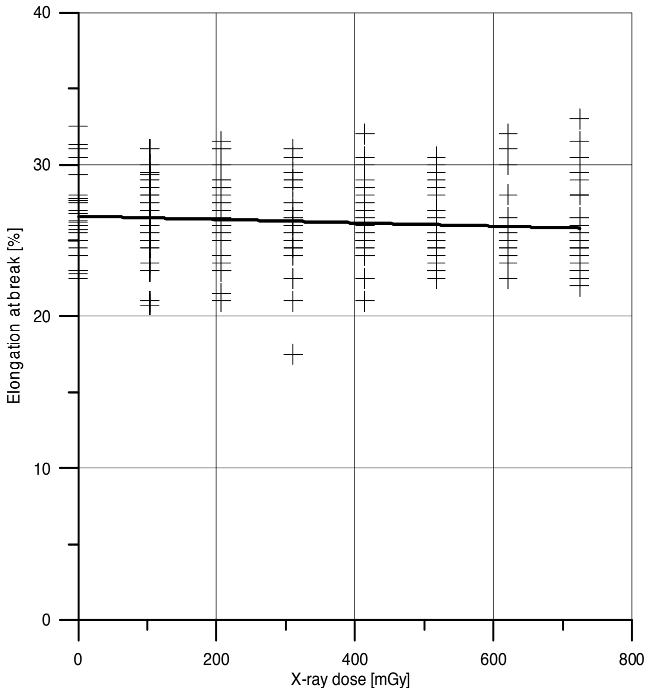


Fig. 8. Dependence of elongation at break on impulse X-ray dose for polyester yarn before sterilization

3.3. Results and analysis

Because of great number of obtained results they will be presented only graphically. Dependence of specific tensile strength on impulse X-ray dose for yarn before sterilization is presented in Fig. 7. Dependence of elongation at break on impulse X-ray dose for yarn before sterilization and is presented in Fig. 8.

Results presented in Figs. 7 and Fig. 8 show that only minute changes of measured properties took place.

Specific tensile strength increased and elongation at break decreased after X-rays exposure. But observed results differences are much smaller than results scatter. Results scatter is typical for fibre testing. That was the reason for which thirty samples were tested. It may be concluded that maximum dose after 70 X-ray impulses did not influence substantially specific tensile strength and elongation at break of tested thermoplastic polyester yarn not subjected to sterilization.

The same results for fibers subjected to sterilization and impulse X-rays irradiation are shown in Fig. 9 and Fig. 10. Here both strength characteristics slight decrease was observed. More pronounced decrease was noticed for specific tensile strength. Once more strength characteristics decrease was within results scatter. Sterilization in accelerated electrons did not change in great extend results obtained for fibers not subjected to sterilization. Sterilization together with 70 impulses of X-rays unit doses did not influence significantly mechanical strength properties of polyester.

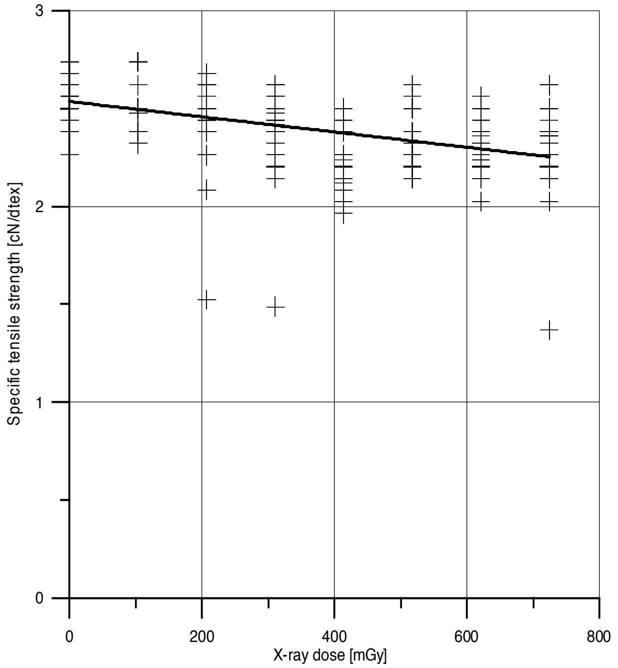


Fig. 9. Dependence of specific tensile strength on X-ray dose (samples after sterilization)

Results of influence of continuous and impulse X-irradiation on specific tensile strength and elongation at break are presented in Fig. 11 and Fig. 12. Analysis of results show low increase of specific tensile strength (0.7%) and small elongation at break decrease (0.8%). Observed changes were several times smaller than results scatter. Also these results confirm that sterilization, continuous and impulse X-irradiation did not change substantially strength and deformation characteristics. Of course this conclusion is valid for doses applied in this research programme. According to literature data [14,15] higher doses are expected to cause substantial changes.

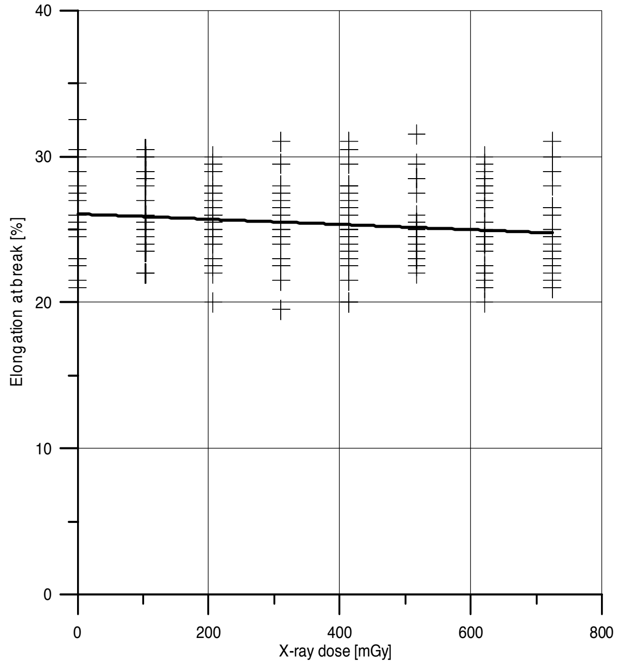


Fig. 10. Dependence of elongation at break on X-ray dose (samples after sterilization)

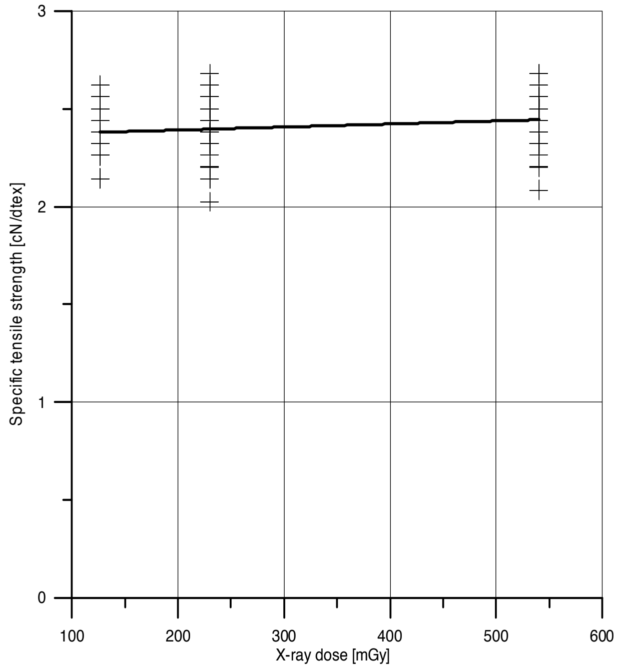


Fig. 11. Dependence of specific tensile strength on X-ray dose (samples after sterilization, continuous and impulse irradiation)

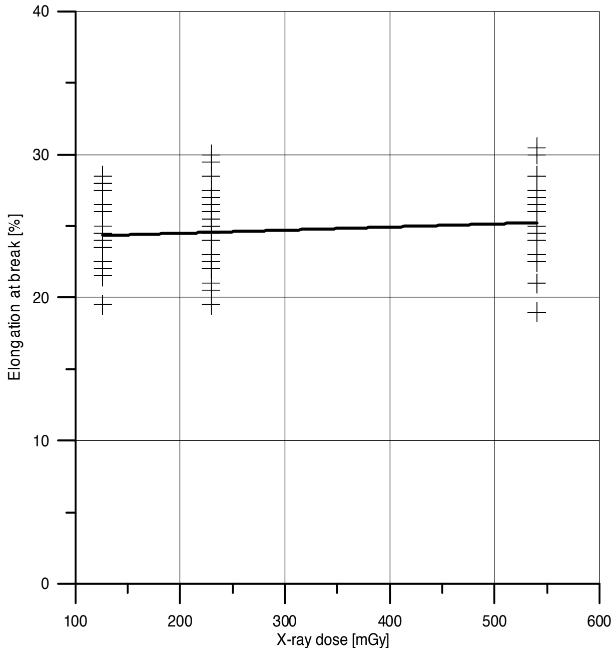


Fig. 12. Dependence of elongation at break on X-ray dose (samples after sterilization, continuous and impulse irradiation)

Fig. 13 and Fig. 14 show summary dependences of strength properties on X-ray dose for polyester yarn before sterilization, after sterilization and after continuous irradiation. Applied dose was in the range from zero to 724.5 ,Gy.

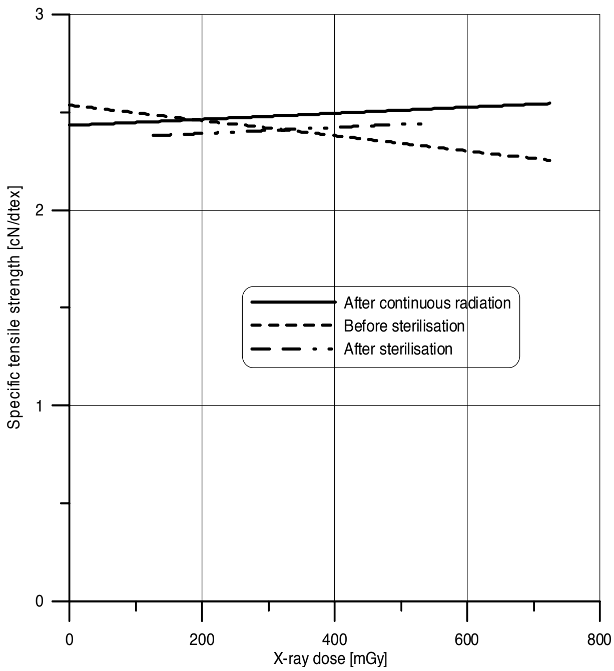


Fig. 13. Comparison of specific tensile strength dependences on X-ray dose for samples irradiated in different ways

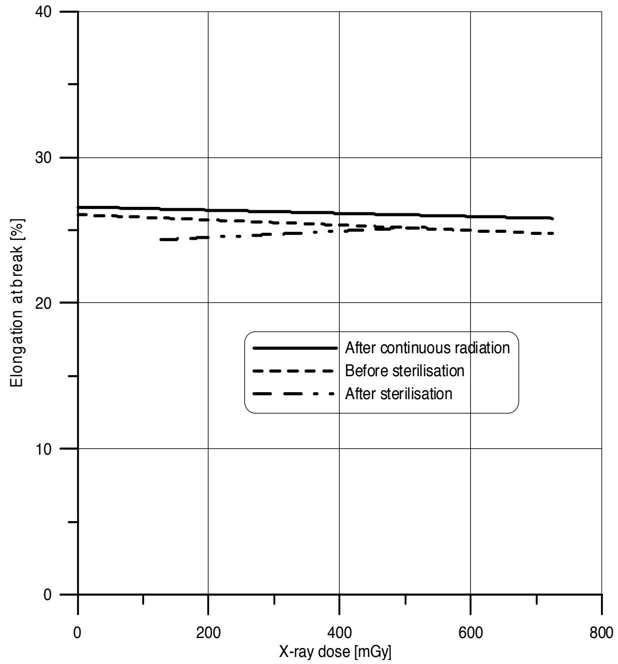


Fig. 14. Comparison of elongation at break dependences on X-ray dose for samples irradiated in different ways

Analysis of all dependences show that X-ray doses in the mentioned range did not show substantial influence on strength characteristics such as specific tensile strength and elongation at break. Observed changes of these characteristics were smaller than results scatter and experimental error. So, there is no anxiety that multiple exposure of patients with polyester vascular system prostheses to radioscopic examination can negatively influence strength properties of these prostheses.

4. Conclusions

- Maximum applied X-ray dose, 724.5 mGy, what is equivalent to 70 unit doses typical for diagnostic radioscopy, did not change substantially strength properties of polyester yarn.
- Observed changes of strength characteristics are smaller than results scatter and experimental error.
- Vascular system prosthesis can be produced from polyester yarn without any danger of mechanical properties loss due to radioscopic examination.

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