STERILIZATION AND PROPERTIES OF BRAIDED SILK SURGICAL THREAD

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The radiation treatment carried out of surgical braided silk thread at the electron accelerator "Electronics U-003." The value of sterilization dose and dependence of breaking load of braided surgical silk thread and a simple surgical knot from absorbed dose is determined. The dependence of the elastic modulus of the thread from the absorbed dose is established.

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1. INTRODUCTION

It is known that the medical devices sterilize for the purpose of preventing the entry of infection in the process of application. At present time for sterilization of devices generally used heat, gas, chemical and radiation methods [1].

It should be noted the absence of a universal sterilization method which acceptable to carry out of sterilization all types of medical devices. Sterilization quality mostly depends on the right choice of the method and equipments of sterilization [2]. Device and packaging materials, the required sterility degree, method capacity and cost of sterilization should be considered when selecting of the sterilization method. Thereby, taking into account its specific for each product must be selected method and sterilization technology. As well known, surgical threads are one of the important medical devices which are requires high sterility due to the specificity of their application. They are used in prosthetic tissues and organs, in cardiovascular, plastic and other areas of surgery where seams need to ensure a reliable connection of synthetic materials and biological tissues [3-4]. After sterilisation should be preserved physical-mechanical, functional properties of threads. As well known, there are resolved and unresolved surgical threads. Absorbable surgical threads are used to accelerate the healing of surgical suture and non-absorbable threads used for tissue fixation for a long period [3,4].

Non-absorbable surgical threads based on synthetic polymers are widely used as suture materials. Non-absorbable threads, which include polypropylene monothreads, may be processed only ethel oxide as strength properties after gamma irradiation deteriorates to 20...30%, and after accelerated electrons to 45...50% [4]. However, lavsan and caprone surgical threads are expediency to sterilize by gas and gamma rays ^{60}Co [4], practically does not change wick and reliability of the surgical node and their strength decreases inessential [4]. One of the unabsorbable (absence of biodegradation) seam materials are threads from the natural silk, which are used in the medical surgery. Silk surgical threads have excellent manipulative properties, high strength and reliability of node. Silk threads are used in general and dermal surgery, in plastic and gastrointestinal surgeries [3-4]. Surgical silk thread sterilizes by gas method [5] and gamma rays [6]. It should be noted that the gaz method sterilization is low-productive and second sterilisation method is relatively expensive because of the high cost of ^{60}Co isotope [7]. Radiation processing of silk thread by electron beam [8] is a highly productive and with the relatively a low prime cost. Therefore, if necessary to sterilize of threads at large quantities is expedient to use accelerated electrons.. However, radiation sterilization of silk surgical threads at the electron accelerator with preserved physical, mechanical, optical and functional properties of threads requires an optimal combination of the electron energy, beam current density and the absorbed dose. The main physical and mechanical properties of threads are sleek surface (not to traumatize the tissue), the strength of the thread length and in the surgical knot and reliability of the surgical knot. Thus, the purpose of this work is determine of the sterilization dose, properties and functional opportunities of woven silk surgical thread after radiation treatment at the electron accelerator.

2. MATERIALS AND METHODS

For the development of radiation technology sterilize of braided surgical silk threads (without needles)

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and studies of the effect of radiation on some its physical properties were selected threads which manufactured according to GOST 5618-80 by company OOO "RTM". Initial braided silk surgical threads were white with a cream shade. Silk threads intended for radiation treatment were divided into 4 parts, and 3 of them were packed in three boxes. Each box had 27 threads on 3 pieces with each conventional numbers, which means of the threads diameter.The fourth box with threads was left as a control.

For investigation of breaking strength and elongation of the test material was used automatic tension testing machine PARAM XLW-PS with microcomputer control. Tension testing machine has a stroke stretching of 1000 mm, speed of stretching - from 25 to 500 mm/min, the accuracy is 0.5%. A simple surgical knot on rubber hollow tube with 6.5 mm diameter knits at testing of knot thread. Thread enfolding the tube was cut in the middle and refuels by long ends in a tensile testing machine clamps. The knot is in middle between of clamps. Determination of the breaking load thread was performed according to GOST 6611.2-73, breaking elongation of thread according to TU 396-84. The distance was 200 mm between clamps; the speed of upper clamp movement is 200 mm/min at the experiments. Swelling of packages monitored visually. The product in consumer package was immersed in water at a depth of 300 mm to check of tightness for 15 seconds. The absence of air bubbles indicates of the packing hermeticity. The radiation processing of silk surgical thread carried out at the multipurpose linear accelerator of electrons "Electronics U-003" in the Institute of Nuclear Physics. Distinctive special feature of accelerator are a wide range of the electrons energy regulation (4...8 MeV), the amplitude, the pulse repetition frequency, a beam current.

Managing by these accelerator parameters allows to choose of the optimum dose sterilization at conservation of physical and mechanical properties. For the uniform treatment of samples at the irradiation area established roundabout with the adjustable of rotation speed from 0.018 rad/s to 0.090 rad/s. Transporter line provides continuous feed of samples to irradiation area. The presence of the controlling high-precision and measuring instruments of radiation doses, quality of materials and items after radiation treatment is one of basic factors at the development of the radiation sterilization technology. Cylinder Faraday with diameter 1sm2 was used for measuring of the accelerated electrons current density. The energy of electrons was determined by using of a standard measuring aluminium wedge (P4701) Riso 2 Piece Aluminum (Belgium) intended for measure of electron energy from 2 MeV to 10 MeV, film type detectors B3110 (USA), spectrophotometer Thermo Genesys 20 [9] with program software Windows for Excell 2002 installed on the personal computer. In the measuring wedge were placed the 30 pieces V3110 type film detectors with 1 mm distance on height (in the depth) strictly perpendicular to the electron beam direction at a distance of 1 m from irradiation source. The optical density of the film detectors absorption with the 552 nm wavelength was measured at the spectrophotometer. The energy of electrons was determined by optical density changing of the B3110 film detectors on Genesys 20 [9] spectrophotometer. B3002 and SO PD(F)R-5/50 type's film detectors were used for metrological support of radiation processes in all stages of radiation treatment. For determining of the absorbed dose the detectors were placed into the box with items which must be sterilized. The microbiological purity of seam surgical silk threads was determined by using Hottinger's agar, thioglycolic medium and Sabouraud's medium.

3. EXPERIMENTAL RESULTS AND DISCUSSION

Silk threads irradiated by electrons at the absorbed doses: 7.2 kGy, 9.2 kGy, 11.4 kGy, 12.1 kGy, 14.1 kGy, 15.2 kGy, 19.1 kGy, 20.0 kGy, 24.3 kGy, 30.1 kGy, and 32.2 kGy. The microbiological analysis of the radiation-processed items showed that at the absorbed doses up to 20.0 kGy the seam surgical threads are nonsterile, and the threads, processed at 20.0 kGy, 24.3 kGy, 30.1 kGy, and 32.2 kGy are sterile. However, at the absorbed dose 24.3 kGy, 30.1 kGy and 32.2 kGy the color of threads and packing changed slightly, i.e. they obtained yellowish nuance. Check out on hydraulic test showed that air tightness of packing was saved in all items. Swelling of packing do not discovered. The experimental results on the tensile testing machine of strength for load and lengthening of threads, and also strength at the simple surgical knot at different absorption doses are given in Table and Fig.1, respectively.

Breaking load and lengthening of the radiation-processed braided silk thread at different absorption doses.

No	Absorbed dose, kGy	Maximal breaking load, N	Relative lengthening, %
1	Initial	48	22
2	7.2	43	20
3	9.2	43	20
4	11.4	42	19
5	12.1	48	22
6	14.1	43	23
7	15.2	43	20
8	19.1	44	23
9	20	45	22
10	24.3	46	21
11	30.1	44	24
12	32.2	46	24

As can be seen from Table that at the 12.1 kGy dose the breaking load is same with initial unprocessed thread, and relative lengthening is 22%. The breaking load decrease with increasing absorbed dose, likely due to degradation of the thread. The dependence of relative lengthening (ε) from applied load for processed thread at the 32.2 kGy dose is given in Fig.2.

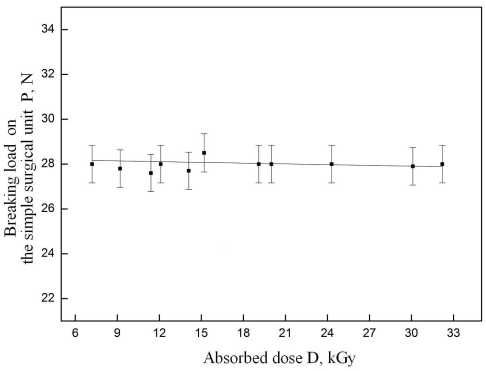

Fig.1. *Strength dependence of the simple surgical knot of silk thread from absorbed dose*

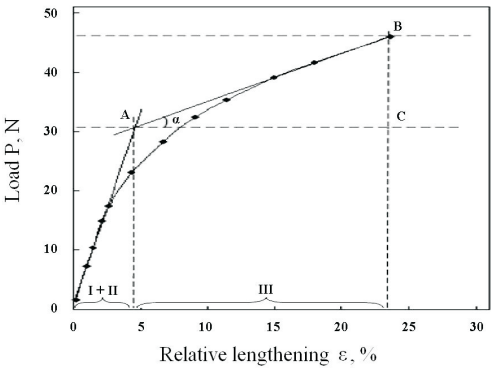

Fig.2. *Dependence of thread relative lengthening from load at* $32.2\,kGy$ *absorbed dose value*

Taking into account the nonlinear nature of this dependence also as in [10], the thread extension process is possible to divide into three phases [10-12]]. The straightening of curved sections occurs in the first phase, in the second phase is observed of the displacement and in the third phase occurs of thread tension [10]. The load value at point A (Fig.2), where intersect tangents, defines of phases tension boundaries. As can be seen from Fig.2, tension-lengthening (III phase) is proportional to increase of applied load which indicate the opportunity of applying Hooke's law and determination of elastic modulus E. Also as in [10], it is possible to determine of elastic modulus E as $tg\alpha$ from the triangle ABC:

$$tg\alpha = \frac{BC}{AC}\,, \tag{1}$$

where, the AC is change of relatively thread lengthening $(\varepsilon_2 - \varepsilon_1)$ in the third section; BC is a change of stress model at III area, which is defined as a difference of load ratios to the thread cross-sectional area S:

$$\sigma_2 - \sigma_1 = \frac{P_2}{S} - \frac{P_1}{S}\,, \tag{2}$$

where P_2 – breaking load; P_1 – value of load at point A; σ_2 – stress at the point of break; σ_1 – stress at point A. S is thread cross-section area:

$$S = \frac{\pi d^2}{4}\,, \tag{3}$$

where d – thread diameter. Taking into account foregoing, the elastic modulus E is equal:

$$E = \frac{4(P_2 - P_1)}{\pi d^2(\varepsilon_2 - \varepsilon_1)}\,. \tag{4}$$

The calculations were carried out for determine of the elasticity modulus also as in [10,12]. The results of thread elasticity modulus dependence from absorbed dose are shown in Fig.3.

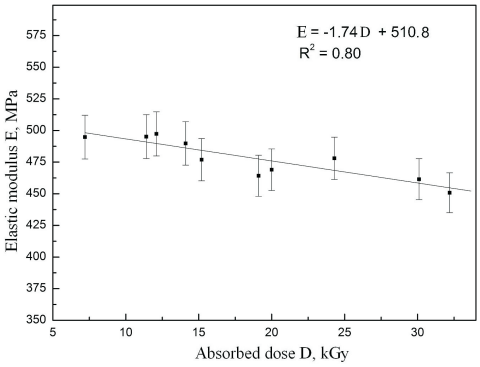

Fig.3. *The dependence of the thread modulus of elasticity from absorbed dose*

It is evident that with an increase of absorbed dose value the modulus of elasticity decreases and the linear nature of elasticity reduction depending from absorbed dose are observed. The dependence of the modulus of elasticity from absorbed dose is described as: $E = -1.74D + 510.8$. Modulus of elasticity of initial sample is $545\,MPa$.

Reduction of surgical thread strength after sterilization was found earlier at [4]. It was found [4] that gas sterilization of polypropylene monothread reduces of strength on 6.1% and still 7% after 540 days storage. According to [4], these threads can be sterilized by gas method. Thread properties changes not only after irradiation, but also after changing of storage temperature. Analysis of the dependence of silk surgical threads strength and elasticity from ambient temperature carried out at [13]. For silk thread with $0.32\,mm$ diameter the initial breaking strength was $567\,MPa$ and relative deformation was 22.5%. After soaking at $-5°C$ to twenty-four hours the breaking strength is $182\,MPa$ and the relative deformation decreased up to 17.5%. Thus, elasticity of thread decreased on 22% [13]. For adsorbed thread Maxon (diameter – $0.44\,mm$), the original breaking strength was $1756\,MPa$. Relative deformation of the thread was 70%. The breaking strength decreased to $579\,MPa$ after soaking at refrigerator, i.e. strength decreasing was 67%. Thread relative deformation also decreased on 37.5%, i.e. elasticity of thread decreased to 46%. According to [13], the decrease of strength and elasticity of the suture is related to the destruction of the material at low temperatures. Table and Fig.1. shows that the breaking load of silk thread and breaking load of simple surgical knot after irradiation treatment changes up to $\sim 13\%$, which indicates about possibility of using electron beam for

surgical silk threads sterilization. Results of thread elastic modulus calculation before and after radiation processing at 20.0 kGy is showed a deviation $\sim 15\%$ from initial value that does not significantly affect its operating characteristics.

4. CONCLUSIONS

Thus, the sterilization dose for braided silk surgical threads from different diameters and lengths is 20.0 kGy in which the strength of thread and a simple surgical knot, as well as lengthening corresponds to acceptable standards. Established the dependence of elastic modulus from absorbed doses allows to determine of upper limit sterilization dose of braided silk thread at conservation of acceptable deviation values of elastic thread. Work is performed within the framework of Grant A10-FA-F130 of Committee on Coordination of Development of Science and Technologies at Cabinet of Ministers of Uzbekistan.

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СТЕРИЛИЗАЦИЯ И СВОЙСТВА ПЛЕТЕННОЙ ШЕЛКОВОЙ ХИРУРГИЧЕСКОЙ НИТИ

М. Ю. Ташметов, Н. Б. Исматов, Р. П. Саидов, Ш. М. Махкамов, Р. Г. Абдульманов, Х. Р. Хабибуллаев

Осуществлена радиационная обработка плетенной хирургической шелковой нити на ускорителе электронов "Электроника У-003". Определено значение стерилизующей дозы и зависимость разрывной нагрузки плетенной хирургической шелковой нити и простого хирургического узла от поглощенной дозы. Установлена зависимость модуля упругости нити от величины поглощенной дозы.

СТЕРИЛІЗАЦІЯ І ВЛАСТИВОСТІ ПЛЕТЕНОЇ ШОВКОВОЇ ХІРУРГІЧНОЇ НИТКИ

М. Ю. Ташметов, Н. Б. Ісматов, Р. П. Саідов, Ш. М. Махкамов, Р. Г. Абдульманов, Х. Р. Хабибуллаєв

Здійснена радіаційна обробка плетеної хірургічної шовкової нитки на прискорювачі електронів "Електроніка У-003". Встановлено значення стерилізаційної дози і залежність розривного навантаження плетеної хірургічної шовкової нитки і простого хірургічного вузла від поглиненої дози. Встановлена залежність модуля пружності нитки від величини поглиненої дози.