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New laser technologies in ophthalmology for normalisation of intraocular pressure and correction of refraction*

O.I. Baum, A.V. Yuzhakov, A.V. Bolshunov, V.I. Siplivyi, O.V. Khomchik, G.I. Zheltov, E.N. Sobol'

Abstract. **We present the results of recent studies that develop principally new approaches to solving the problem of visual impairment and provide the basis for new laser technologies in ophthalmology for the treatment of glaucoma, myopia and hypermetropia. The considered theoretical models and optical methods for detecting laser-induced structural changes in eye tissues pave the way to the invention of control systems with feedback, providing efficient and safe laser treatment.**

Keywords: *laser, glaucoma, refraction, thermotensions, optical methods, structural changes.*

1. Introduction

The results presented in this paper continue and develop new efficient approaches to solving the problem of visual impairment using the methods of laser-induced modification of eye tissues. A positive effect of laser impact is achieved, as a rule, in a narrow range of laser radiation parameters, which makes it difficult to choose the energy and time parameters of laser irradiation due to such factors as nonstationary temperature fields, thermotensions and pressure that can give rise to undesirable effects and complications.

Refraction abnormalities and glaucoma are the most frequent eye diseases, for the treatment of which lasers have been used for more than 40 years [1]. The most widespread methods of treatment are the keratorefraction operations, such as the photorefractive keratectomy (PRK), in which the local surface destruction of cornea is produced [2], and the laser *in situ* keratomileusis (LASIK) [3]. To treat the hypermetropia use is also made of laser thermal keratoplasty (LTK), in which the change of refraction is achieved by the coagulation and shrinkage of peripheral cornea under the impact of laser radiation, due to which the curvature radius of the cornea is changed [4]. Unfortunately, the results of such operations are poorly predictable and insufficiently stable, since with time an essential regress of the positive effect occurs due to the regeneration processes in the damaged eye tissues. The growing requirements to the post-operation results determine the necessity of developing new laser technologies for ophthalmology [5, 6].

Earlier it was shown that the laser-induced relaxation of stresses in the eye cornea allows the purposeful change in its shape. This is the basis of a new technology of correcting myopia, hypermetropia and astigmatism of the eye [7–10], and the formation of a porous structure in the sclera allows an increase in the fluid drainage through the sclera and the normalisation of the intraocular pressure [11, 12].

Thus, the goals of the present paper are to present the results of theoretical modelling that allow one to determine an optimal range for the parameters of the impact on the sclera and cornea, as well as to study structural changes in laser-modified samples of eye tissues.

2. Normalisation of intraocular pressure by enhancing the intraocular fluid filtering under the impact on the sclera in the projection of pars plana of the ciliary body

Primary open-angle glaucoma (POAG) is the most frequent kind of glaucoma in adults (70% of all patients suffering from glaucoma). In this case, the excessive intraocular pressure is related to the impairment of fluid outflow through the drainage system of the eye because of the Schlemm's canal blockade and dystrophic changes in the trabecula and intrascleral canals. POAG is present in 1%–2% of the population above 60 years old, which makes it urgent to develop new laser technologies.

Besides the drug treatment, laser operations are also used, the most widespread one being selective laser trabeculoplastics (SLTP) proposed by M. Latina in 1995. It consists in the impact of laser radiation on the trabecular zone in the projection of the Schlemm's canal [13]. During SLTP coagulating effect in the structures is absent. Pulses are directed onto the trabecula zone, and due to the large size of the laser beam spot (400 μm for selective trabeculoplastics and 50 μm for the traditional one) the laser radiation interacts with the entire trabecula rather than with the projection of the Schlemm's canal, eliminating both the blanching zones and the 'popcorn effect'. This causes both the sparing effect of the method and its insufficient efficiency [14]. The less widespread operation of

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O.I. Baum, A.V. Yuzhakov, E.N. Sobol' Institute of Photon Technologies, Federal Scientific Research Centre 'Crystallography and Photonics', Russian Academy of Sciences, Leninsky prosp. 59, 119333 Moscow, Russia; e-mail: baumolga@gmail.com;
A.V. Bolshunov, V.I. Siplivyi, O.V. Khomchik Federal State Budgetary Scientific Institution 'Scientific Research Institute of Eye Diseases', ul. Rossolimo 11A, 119021 Moscow, Russia;
G.I. Zheltov B.I. Stepanov Institute of Physics, National Academy of Science of Belarus, prosp. Nezavisimosti 68, 220072 Minsk, Belarus

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laser diode cyclocoagulation is based on the local destruction of the ciliary body, which in the case of insufficiently exact choice of the laser irradiation parameters (often depending on the particular structure of the patient's ocular system) can lead to the local formation of thrombi in small and medium blood vessels and haemorrhages [15].

Thus, the presently existing laser methods of glaucoma treatment have limitations and side effects, which stimulates the search for new technologies.

It is known that alongside with the mass transfer of the intraocular fluid (IOF) through the Schlemm's canal and the vascular system of the eye, an alternative natural mechanism exists, namely, the uveoscleral outflow [16], transferring up to 50% of intraocular fluid in children, but less than 3% in adults [17]. The presence of the uveoscleral outflow of the IOF in humans was described for the first time in 1965 [18]. Later is was shown [19] that from the perichorioidal space the fluid not only outflows to the vascular bed of the uveal tract, but also diffuses directly outwards through the sclera thickness. The control of the transscleral fluid filtering process is an urgent problem.

Nonuniform laser heating affects the porous system of biological tissues [12]. The formation of new pores in the paralimbal region of the eye can accelerate the flow of the intraocular fluid through the eye sclera and, thus, facilitate the normalisation of the intraocular pressure [20, 21].

A new approach to the normalisation of intraocular pressure, based on the thermomechanical laser impact on the porous structure of the eye sclera in the projection of pars plana of ciliary body, leads to the formation of intrascleral microchannels, which results in a considerable increase in the intraocular fluid outflow and normalisation of the intraocular pressure [11].

In a series of *ex vivo* experiments, the selected samples were studied using a special setup for hydraulic permeability measurement, constructed by A.I. Omel'chenko and described in Ref. [22]. The results of sclera hydraulic permeability measurements under the contact impact of repetitively pulsed laser radiation with a wavelength of 1.56 μm have shown that a maximal increase in the eye sclera hydraulic permeability in the experimental animals compared to the intact tissue is achieved at a laser power density of 1.8 W cm^{-2}, a pulse duration τ = 200 ms, a pulse repetition rate of 2.5 Hz and an exposure time of 4 s [23].

With the above analysis and the differential scanning calorimetry (DSC) in the temperature interval 25–100 °C, it was shown that for the chosen regime of laser action the changes in the irradiated tissue are related to the structural changes rather than to the collagen coagulation [7–11].

The *in vivo* experiments were carried out in 8 right eyes (the left ones left intact for control) of 8 Chinchilla Grey rabbits weighting from 2 to 2.5 kg. Four animals were taken out from the experiment immediately after the laser impact, and the rest ones in 45 days after it. The study of the hydraulic permeability dynamics of the sclera samples *in vivo* under the contact impact of repetitively pulsed radiation (λ = 1.56 μm) in the projection of pars plana of the ciliary body confirmed a significant increase in the hydraulic permeability in the chosen optimal regime and the conservation of the result during 45 days [24].

For the preliminary determination of the regimes that were used in the *in vivo* experiments the heat conduction equation was solved with a volume heat source $G(x,y,z,\tau)$ produced by the laser radiation and decaying with depth according to the Bouguer–Lambert–Beer law with the effective absorption index κ:

$$\frac{\partial T(x,y,z,\tau)}{\partial \tau} = a\Delta T(x,y,z,\tau) + G(x,y,z,\tau), \tag{1}$$

where a is the thermal diffusivity. The density of the energy flux incident on the transverse surface of the cartilage tissue has the spatial distribution that corresponds to the Gaussian one with the effective beam radius $r_0(x)$, with allowance for the transverse divergence of the beam in the process of propagation through the medium in the x direction:

$$G(x,y,z,\tau) = P(\tau)\exp\left[\frac{y^2+z^2}{r_0^2(x)}\right]\frac{\kappa\exp(-\kappa x)}{c\rho}, \tag{2}$$

where $P(\tau)$ is the time-dependent power density of the laser radiation; c is the specific heat capacity; and ρ is the density.

Because of the complex geometry of the problem, it was impossible to solve the heat conduction equation (1) analytically, and for the numerical solution the finite-difference method (grid method) was used, in which the derivatives are replaced with their approximate values expressed in terms of the finite differences of the function values at the grid nodes. The numerical modelling was carried out using the Frankel–Dufort scheme [25] with three time layers implemented in the 'Mathematica' software package.

Figure 1 presents the time dependence of the maximal temperature under the laser impact with different power for the temporal regime 200 ms, 2.5 Hz, 4 s. The total time of the sample being at a temperature above 70 °C equals 0.5 s for the power 0.7 W, 2 s for the power 0.9 W and 2.8 for the power 1.1 W. However, the satisfactory average temperature, corresponding to the heating to about 70 °C, was obtained with the irradiation power 0.9 W, while the power below 0.8 W resulted in underheating, and the power above 1 W produced obvious overheating, leading to denaturation.

For the chosen average power 0.9 W, the simulation of the impact regimes for the laser pulse durations of 100, 200 and

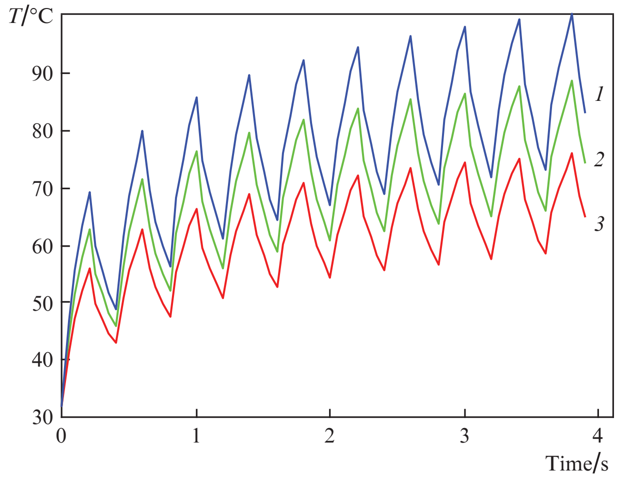

Figure 1. Dynamics of the maximal temperature under the laser impact with an average power of (*1*) 1.1, (*2*) 0.9 and (*3*) 0.7 W (the pulse duration is 200 ms, the repetition rate is 2.5 Hz and the irradiation time is 4 s).

300 ms was carried out (Fig. 2). The total time of the temperature being higher than 70 °C was equal to 3.45 s for a pulse duration of 300 ms, 2 s for 200 ms, and for 100 ms the temperature was below 70 °C during the entire exposure. The satisfactory average temperature that allows one to maintain the temperature about 70 °C was achieved only with a pulse duration of 200 ms and a pulse repetition rate of 2.5 Hz. The behaviour of the obtained dependences of the maximal temperature agrees well with the experimental data for the laser heating of eye tissues [26]. Thus, the theoretical modelling allows the prediction of the range of laser parameters, in which one can expect the existence of the desired result of the laser impact.

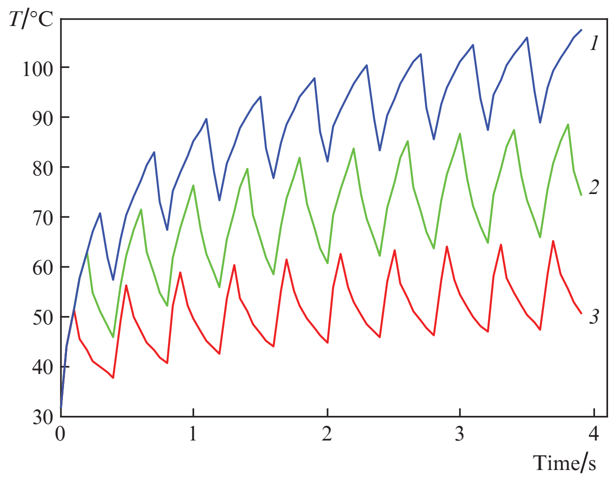

Figure 2. Dynamics of the maximal temperature under the laser impact with a power of 0.9 W for a pulse duration of (*1*) 300, (*2*) 200 and (*3*) 100 ms (the repetition rate is 2.5 Hz and the irradiation time is 4 s).

The structural changes in the sclera under the impact of nondestructing laser irradiation in the regime of increasing the hydraulic permeability were studied using atomic force microscopy (AFM). Three zones were selected for the study: the intact zone, the 'discharged' zone around the laser beam spot and the zone directly overlapped by the laser beam spot.

The mathematical processing of the AFM images has shown that in the intact tissue the mean size of micropores amounts to 14 ± 3 μm. For the tissue located directly in the irradiated area the micropores size is 25 ± 5 μm, and at the periphery of the laser irradiation, where the stresses were maximal, the mean size of micropores amounts to 35 ± 5 μm. Thus, the laser irradiation leads to the formation of additional pores and the enlargement of the already existing ones at the periphery of the laser irradiation zone.

The AFM study of the surface relief allowed the structure periodicity to be studied along and across the collagen fibres for the case of intact tissue (Fig. 3) and the tissue in the zone of maximal stresses after the laser impact (Fig. 4). The presented periodicity of the fibrous structure agrees well with the data reported earlier in Ref. [27]. The comparison of the results presented in Figs 3 and 4 shows that under the laser impact, the separations between the fibrils increase, while their arrangement remains periodic.

The performed experiments have shown that the nonuniform heating with repetitively pulsed laser radiation allows the hydraulic permeability of the tissues to be increased in the

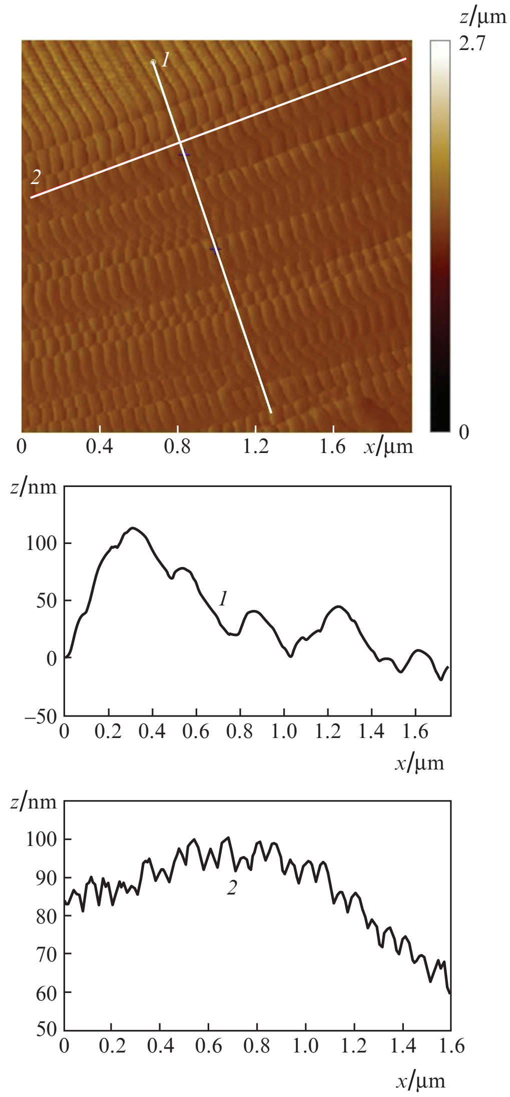

Figure 3. AFM profile of the surface relief of the intact sclera (*1*) along and (*2*) across the fibrous structure (along the lines shown in the top view).

paralimbal region of the eye sclera by 20–30 times. The effect is achieved only by using relatively small powers of radiation. At high powers, the hydraulic permeability decreases due to denaturation and tissue hardening [28]. An increase in the hydraulic permeability of eye tissues is caused by the formation of a system of micropores due to the effect of laser radiation.

Using the presented technique, the clinical studies were carried out at the Scientific Research Institute of Eye Diseases (FSBSI RIED) that confirmed the stability of the result during 12 months [24].

Thus, a significant increase in the sclera hydraulic permeability in the paralimbal region of the eye is proved experimentally. The durability of the effect is the subject of further studies.

3. Correction of the eye cornea shape under the thermomechanical action of laser radiation

A new approach to correcting refraction, the mechanism of which is based on modifying the structure and the field of

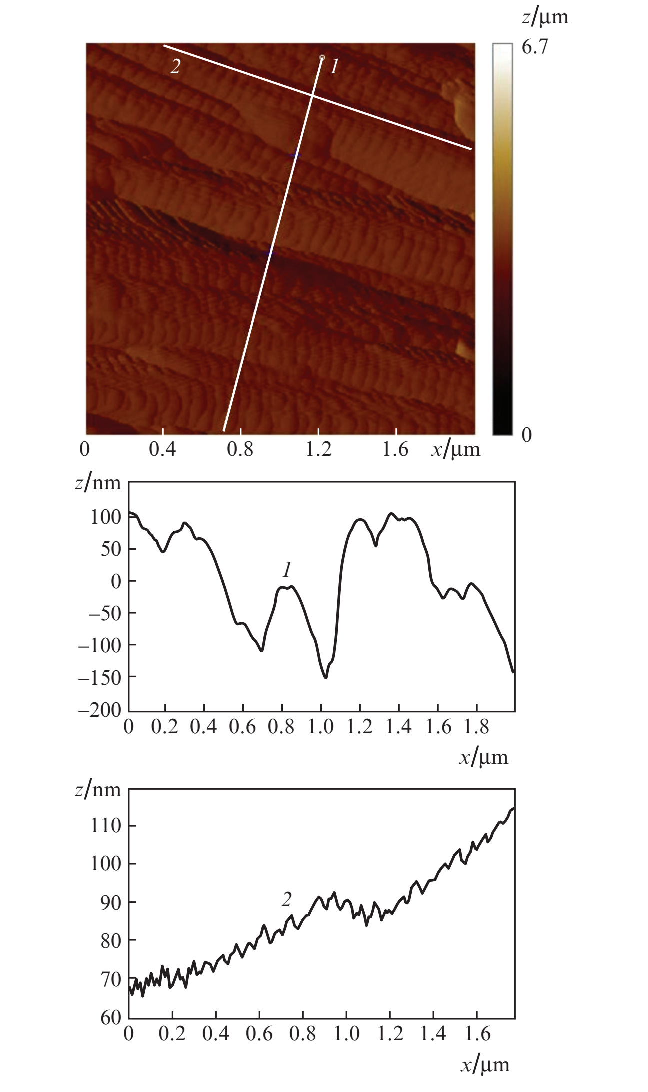

Figure 4. AFM profile of the surface relief of the sclera sample in the zone of maximal stress after the laser irradiation in the 'optimal' regime (*1*) along and (*2*) across the structure (along the lines shown in the top view).

mechanical stresses in eye cornea under nonablative laser impact was proposed in Refs [5–10]. The thermal stability of the cornea was studied in Refs [29–32]. It was shown that the short time heating of the cornea to the temperature of 50–60 °C could provide a change in its plasticity without damaging the collagen structure and a change in transparency. These results formed the grounds of a new nondestructing technique of laser correction of the cornea shape, which, in contrast to the laser thermoplastics (leading to the coagulation and shrinkage of the cornea) is not related to the collagen denaturation.

It as established that the local exposure of the sclera to cw laser radiation (λ = 1.56 μm) allows a change in eye refraction by nearly 3 dioptres [5, 6], whereas sequential laser irradiation of sclera and cornea leads to a more essential (to 7 dioptres) change in eye refraction [7].

In further *in vivo* experiments, it was shown that the average value of the refraction change is lower than in *in vitro* experiments, and in 10 days after the laser impact it amounted to 2.5 ± 0.5 dioptres. The comparison of *in vivo* and *in vitro* experimental results [33] has shown an essential influence of the intraocular pressure on the laser-induced change in the eye cornea shape.

The result of laser correction of the cornea shape depends on the geometry of the incident laser radiation. An asymmetric point-by-point impact leads to an asymmetric cornea shape, which may cause astigmatism, but, on the other hand, can be used for the astigmatism treatment [34].

Since 2010 for this method of refraction correction we have used a source of laser radiation (λ = 1.56 μm) with a ring-shaped distribution of intensity ('ring source') [35]. This provides the axial symmetry of the impact and eliminates the appearance of astigmatism. For the ring-type distribution of the laser radiation intensity with a maximum at the cornea periphery, the temperature of the cornea surface also possesses a ring-shaped distribution, which causes axially symmetric stresses in the cornea leading to axially symmetric deformations.

The temperature was measured using a Testo-875 infrared imager in 4 s after the beginning of laser irradiation with the pulse duration 500 ms, the repetition rate 1.2 Hz, the radiation power 2.2 W and the separation between the radiating laser head and the cornea 8.4 mm. The maximal change in the temperature amounted to 12 °C at the cornea periphery and 9 °C in the centre, which was confirmed by the calculations. Thus, the ring-shaped distribution of radiation leads to stronger heating of cornea at its periphery than in the central zone. The theoretical and experimental study of the dynamics of the temperature field redistribution due to the heat conduction, leading to an increase in temperature in the central zone after the end of irradiation, has shown that the achieved maximal temperature in the centre does not exceed the peripheral temperature at the time of heating termination.

The applicability of the new technique for modifying the eye refraction can be checked using theoretical models that allow the laser irradiation consequences to be predicted and the required irradiation parameters to be chosen.

4. Model of eye refraction change under the nonablating laser impact on the sclera

This model approximately describes the cornea strain due to the change in the total sclera tissue volume under its local coagulation. It is based on the idea that the inner eye volume and the volume of sclera and cornea remain unchanged and that the denaturation of collagen in the sclera tissue is accompanied by 50 % shrinking on average [36].

The volume of sclera coagulation is determined as the product of the number of irradiated zones, the area of each zone and the depth of the heated sclera layer depending on the thermal diffusivity and the time of exposure. At the same time, this volume is expressed in terms of the inner sclera radius, its thickness and the radii of the base of the cornea spherical segment before and after irradiation. The variation in eye refraction can be calculated by equating both expressions for the coagulation volume. In the first approximation, this model yields the dependence of the eye refraction change in dioptres on the laser irradiation parameters.

5. Model of corneal stress relaxation

The mechanism of stress relaxation in the cornea is due to the local islands of intact collagen fibres conserved in the zone of laser-induced sclera denaturation. When the irradiated zone is constricted, they move towards its centre and give rise to the cornea strain, leading to its flattening and causing a change in refraction, as shown earlier using the methods of polarisation-sensitive optical coherence tomography [9]. Simultaneous noninvasive laser impact on the cornea itself leads to the plastic deformation and, as a result, to the relaxation of stresses. In this case during the cooling the residual stresses and the irreversible residual deformation arise, which is a cause of the cornea shape change.

Since the acting laser beam spot has a Gaussian intensity distribution, the temperature of the cornea heating will decrease towards the spot edge. The irradiated regions of the cornea are subjected to different impacts depending on the distance from the laser beam spot centre, and on achieving the temperature at which the relaxation of stresses occurs, the region of thermoplastic strain appears where the stresses were maximal.

The two-dimensional thermoelasticity problem was considered for the temperature field produced in the cartilage plate in the process of laser heating, which has the following analytical solution for the radial and angular component of the thermally induced stress, respectively:

$$\sigma_r = \alpha E\left[\frac{1}{b^2}\int_0^b T(r)r\mathrm{d}r - \frac{1}{r^2}\int_0^r T(r)r\mathrm{d}r\right],$$

$$\sigma_\theta = \alpha E\left[-T(r) + \frac{1}{b^2}\int_0^b T(r)r\mathrm{d}r + \frac{1}{r^2}\int_0^r T(r)r\mathrm{d}r\right],$$

where b is the boundary of the integration domain for the radial variable r; α is the thermal expansion coefficient; and E is the elastic modulus. The temperature function $T(r)$ was specified in the form of a two-humped function with a maxima at the cornea periphery and a dip in the centre by 25% of the maximum.

The solution of the equilibrium differential equations in the cylindrical system of coordinates allowed the formulation of analytical expressions for the radial and angular components of the stress in terms of the thermal expansion coefficient and the elastic modulus. The domain of plastic deformations in solids is determined by the Mises criterion $\sigma_\theta - \sigma_r = \sigma_s$, where σ_s is the stress, corresponding to the yield point.

The calculations of the temperature field and the corresponding thermal stresses for the eye cornea and the use of the Mises criterion for the ring-shaped intensity distribution of the laser source (for a temperature increase by 12–15 °C at the periphery of the cornea) for the yield point of the cornea equal to 1 MPa ensure the temperature of stress relaxation of 58 °C. This is in satisfactory agreement with the experimentally measured temperature 50 °C of the cornea, at which the laser-induced change in its shape occurred. Due to the short time character of the laser impact, the cornea preserved its transparency, and no denaturation of the tissues of the anterior and posterior part of the eye occurred [9].

For the ring-shaped source, the absolute value of the difference between the angular and radial components of the thermally induced stress tensor, corresponding to the experimentally measured temperature profile at the moment of achieving the temperature maximum, is presented in Fig. 5.

Thus, it is shown that since the heating of the cornea occurs at the periphery and does not involve the central zone, the difference of the angular and radial components of the thermotension inside the ring appears to be smaller than outside by an order of magnitude. This fact provides the safety of the laser procedure that does not affect the central zone of the cornea.

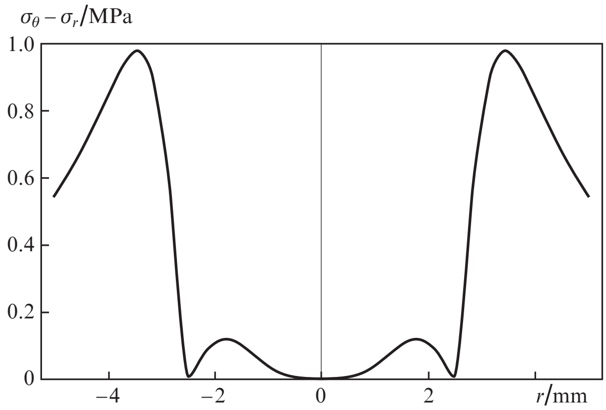

Figure 5. Difference of angular and radial components of the thermally induced stress tensor vs. the distance from the symmetry axis of the eye, coincident with the axis of the ring-shaped radiation source.

6. Optical methods of detecting the structural changes in eye tissues

The efficiency and safety of laser invasion in ophthalmology depends on the choice and usage of the laser radiation optimal parameters. However, even for the chosen regime, the absorption may appear stronger and occur in a wider spectral range due to multiphoton absorption and the appearance of new absorption levels due to the structure inhomogeneities. This causes the necessity of designing control systems with feedback that allow the situation to be controlled in real time. Omel'chenko et al. [37] demonstrate the promising potentialities of developing intellectual laser medical systems that imply the introduction of the automatic feedback in a laser device to implement the optimal control of radiation interacting with a biological object. The basis for such control

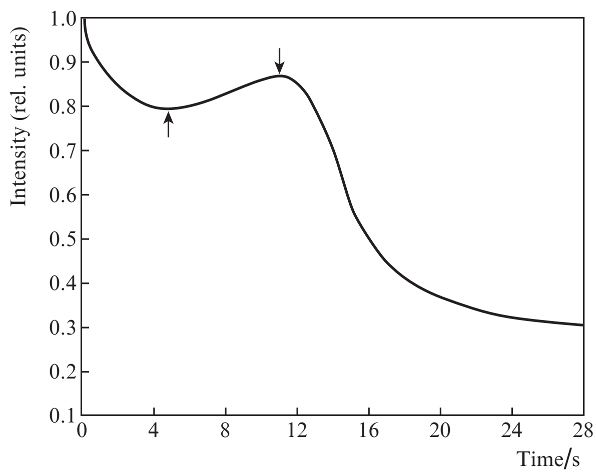

Figure 6. Typical dynamics of the signal with λ = 1.56 μm transmitted through the sample of the paralimbal region of the enucleated eye of a mini pig (Svetlogorsk population, breeding by the Scientific Centre of Biomedical Technologies, Russian Academy of Medical Sciences). The arrows point at the extrema. The curve corresponds to the irradiation in the cw regime with a power of 0.4 W.

systems can be provided by optical methods of detecting structural changes in eye tissues under the laser impact by tracing the dynamics of light scattering in the eye cornea and sclera.

To carry out the experiments on the dynamics of radiation scattering and transmission, a special optical fibre system was assembled that allowed simultaneous sample irradiation with two wavelengths 1.56 and 0.53 μm [38]. The obtained dynamics of a time-dependent transmitted IR signal possessed extrema characterising a possible occurrence of structural changes in tissues. When the parameters of laser radiation were changed, these extrema shifted in time (Fig. 6).

With an increase in laser power or pulse duration, the extrema of the signal shift to the right. The experiments on hydraulic permeability for the chosen regimes have shown that the maximal hydraulic permeability occurs at the first descending region of the plot. Thus, a change in the dynamics of the signal intensity allows one to determine the moment when the desired structural changes are achieved. This principle can be a basis for the control systems with feedback.

Thus, the possibility of correcting the cornea and increasing the sclera hydraulic permeability due to the nondestructing thermomechanical impact of laser radiation is experimentally proved. The durability of the positive effect is the subject of further studies. The obtained results provide a reliable basis for the application of new laser technologies in ophthalmology for the treatment of glaucoma, myopia and hypermetropia. The collection of theoretical models and optical methods detecting the structural changes in eye tissues under laser irradiation makes it possible to produce control systems with feedback, ensuring the efficiency and safety of the laser treatment.

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