

Efficacy of Low-Intensity Laser Therapy Using MACDEL-08 Device in Complex Treatment of Primary Open-Angle Glaucoma

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The aim of the investigation was to evaluate the clinical efficacy of low-intensity laser therapy (LILT) using HeNe laser-based MACDEL-08 device in complex treatment of primary open-angle glaucoma.

Materials and Methods. The LILT was performed to 16 patients (25 eyes) aged 58–78 years with II (group 1) and III (group 2) stages of primary open-angle glaucoma and normalized level of intraocular pressure without anti-hypertensive regimen. 6–18 months before LILT, all patients underwent surgical treatment (sinus trabeculectomy) and a course of conservative therapy (3 months after glaucoma surgery). LILT was performed using MACDEL-08. The course of treatment consisted of 10 daily sessions of 10 min each. All patients underwent visual acuity testing and ocular hemodynamics examination by transpalpebral rheophthalmography before and after LILT. Three basic hemodynamic parameters were calculated: rheographic index, period of maximum filling, index of elastic modulus.

Results. Upon completion of the LILT course, improvement of visual acuity has been noted in all patients, in group 1 from 0.4–0.9 to 0.5–1.0; in group 2 from 0.1–0.8 to 0.3–1.0; $p < 0.05$. The analysis of rheographic parameters has shown the reduction in the deficit of eye tissue blood supply and improvement of elastic properties of the intraocular vessel walls during LILT and after it.

Conclusion. The application of LILT using NeHe laser-based MACDEL-08 device is a harmless, clinically effective, physiologically justified and technically simple component of primary open-angle glaucoma complex treatment.

Key words: primary open-angle glaucoma; MACDEL-08 device; low-intensity laser therapy; transpalpebral rheophthalmography.

In economically developed countries, primary open-angle glaucoma (POAG) as a cause of low vision and blindness occupies the first place in the structure of eye pathology, leaving behind diabetic retinopathy and age-related macular degeneration [1]. A high prevalence of POAG and a social significance of its treatment determine a wide interest to searching for novel and improving existing methods of treatment of this ophthalmic pathology. In spite of the fact that a target level of intraocular pressure has been achieved by means of drugs or surgical treatment, involuntal and metabolic disorders, alterations of cerebral circulation, reduction of antioxidant system activity result in gradual impairment of visual functions in all patients with POAG. Neuroprotectors, antisclerotic and vasoactive drugs, biostimulators, vitamins and antiaggregants as well as various physiotherapeutic methods are used to correct these disturbances [2].

In recent years, low-intensity laser radiation became widely used in medicine in different pathological conditions of the organism. This radiation is characterized by low side-effects, possibility of combined applications with other therapeutic means, positive influence on pharmacodynamics and pharmacokinetics of medicinal preparations. Radiation of HeNe laser of low power (up to 20 mW with 0.63 μm wavelength) can influence the triggering mechanisms of cellular regulation, alteration of cellular membrane condition with the enhancement of cell functional activity [2, 3].

Physiotherapeutic action on the eye structure by a low-power laser radiation results in activation of cellular metabolism, improvement of ocular hemodynamics, and trophic support to eye tissues. In this connection it seems reasonable to use this type of exposure as one of the components of complex treatment of patients with POAG.

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Currently, MACDEL-08 device (MACDEL-Technologies, Russia) is being used for laser therapy of sensor disorders. Its principle of action consists in projecting onto the eye retina a laser speckle-structure, which possesses a contrast and speckle size sufficient for perception by a vision system with a reduced vision acuity to 0.02 (See the Figure). This stimulates the development of central vision in various forms of impaired sight. In contrast to similar devices operating on the basis of semiconductor lasers and light emitting diodes, MACDEL-08 uses gas helium-neon laser with a very narrow spectral radiation band, which influences the contrast of the observed speckle pattern. Such laser allows substantial reduction of procedure duration with a simultaneous increase of a useful radiation dose. Owing to these characteristics, the efficacy of treatment using MACDEL-08 surpasses dozens of times that of its analogs [4]. However, this device has not been applied till present time for stimulation of visual functions in patients with POAG.

A new technique of transpalpebral rheophthalmography enables ophthalmologists to assess objectively the state of blood flow in the main hemodynamic eye system, uveal tract. Its principle is based on the registration of the impedance changes, when high-frequency electrical current is running through the eye tissues [5].

During transpalpebral rheophthalmography, electrodes are applied to the closed eyelid, and in order to make investigations more precise, the bipolar method was replaced by the tetrapolar one, which takes into consideration specific anatomical structure of the eyeball bloodstream. Four reusable metal electrodes 4 mm in diameter, as well as a substrate with the elements for their fixing and positioning are the main elements of the tetrapolar lead system. A construction in the form of elastic helmet, especially developed for investigations, provides fixation of the lead system on the head with the possibility of adjusting it for each patient, as well as the correct location and force for pressing electrodes to the upper eyelid.

During investigations, a patient is in the lying position, the electrode system is mounted on the closed eye and is fixed by the elements of the knitted helmet, the second eye remains open during this procedure to diminish the number of involuntary eye movements, which essentially increase the number of artefacts in the registered signal. Signal registration lasts about 2 min.

After registration, processing and analyzing the recorded rheophthalmogram signals, values of the three main hemodynamic parameters are obtained: rheographic index (RI) reflecting the value of systolic blood inflow and depending on the magnitude of the stroke output and on the vessel tone (in milliohms); the period of maximum filling (PMF) increasing in tone elevation and decrease of vessel elasticity (in seconds); index of elastic modulus (IEM) characterizing structural properties of vessel walls, their elasticity and tone [5, 6].



MACDEL-08 device

The aim of the investigation was to evaluate the clinical efficacy of low-intensity laser therapy (LILT) using HeNe laser-based MACDEL-08 device in the complex treatment of primary open-angle glaucoma.

Materials and Methods. LILT was conducted in Glaucoma Unit of Moscow Helmholtz Research Institute of Eye Diseases. 16 patients (25 eyes) with POAG stage II and III with normalized intraocular pressure without hypotensive regimen were included into the study. Patients were at the age of 58–78 years (mean age 68.13 ± 6.63 years). There were 9 women (56.25%) and 7 men (43.75%). All patients underwent surgical treatment (sinus trabeculectomy) 6–18 months before LILT with the following course of conservative therapy (3 months after antiglaucoma operation) including administration of antioxidants, vitamins of B group, antiaggregants, and neuroprotectors.

POAG patients were distributed according to the stages in the following way: stage II in both eyes in 3 patients; stage III in both eyes in 2 patients; stage II in one eye and stage III in the paired eye in 4 patients; stage II in one eye in 4 patients and stage III in one eye in 3 patients. 7 eyes were not included in the study as one of them was without ophthalmic pathology, POAG stage I was diagnosed in 3 eyes, and 3 more eyes were at stage IV. Two groups were formed: group 1 included 14 eyes with a developed (II) POAG stage; group 2 consisted of 11 eyes with a far-advanced stage (III) of POAG.

The study complies with the Declaration of Helsinki (the Declaration was passed in June 1964, Helsinki, Finland and revised in October 2000, Edinburgh, Scotland) and was performed following approval by the Ethic Committee of Moscow Helmholtz Research Institute of Eye Diseases. Written informed consent was obtained from every patient.

LILT was performed with the help of MACDEL-08 device for activation of cellular metabolism, improvement of ocular hemodynamic indices, and trophic support to eye tissues in POAG patients. Patients watched a moving speckle generated by HeNe laser radiation ($0.63 \mu\text{m}$ wavelength). The course of treatment consisted

of 10 daily sessions of 10 min each. Vision acuity testing and ocular hemodynamics examination using transpalpebral rheoophthalmography were conducted prior to LILT, immediately upon the completion of the treatment, and 2 weeks after the course of LILT. The follow-up period for 11 patients (17 eyes) was 6 months, and for 5 patients (8 eyes) 3 months. It included a full ophthalmological examination with the determination of all hemodynamic parameters by the described method once a month.

The program package Statistica 6.0 was used for data analysis. Statistical parameters were calculated using a method of variational sequences. Student's t-test was used for parametric analysis for comparing mean values of dependent samples.

Results and Discussion. Vision acuity with correction before LILT was from 0.4 to 0.9 (0.65 ± 0.19) in group 1, and from 0.1 to 0.8 (0.48 ± 0.23) in group 2. LILT procedures with MACDEL-08 were well tolerated by all patients. Already on days 3–5 after the therapy onset, 12 patients noted a subjective improvement of visual acuity. Upon the completion of the LILT course, all patients were noted to have a better vision acuity, which was from 0.5 to 1.0 (0.81 ± 0.18) in group 1; and from 0.3 to 1.0 (0.65 ± 0.23) in group 2; $p < 0.05$. The achieved level was preserved for 3 months (5 patients, 8 eyes) and for months (11 patients, 17 eyes) of further follow-up without changes.

Processing of transpalpebral rheoophthalmography data showed RI increase in group 1 from 12.69 ± 1.26 mOhm before LILT to 14.43 ± 1.20 mOhm after the end of the course; PMF decreased from 0.27 ± 0.02 to 0.23 ± 0.02 s, IEM also decreased from 0.31 ± 0.02 to 0.28 ± 0.02 s.

In group 2, RI was found to increase from 9.56 ± 0.89 to 11.33 ± 1.23 mOhm, PMF decreased from 0.31 ± 0.03 to 0.28 ± 0.02 s, IEM diminished from 0.34 ± 0.03 to 0.30 ± 0.02 s. The achieved level of rheogram values remained unchanged in patients for 3 months (5 patients, 8 eyes) and 5 months (11 patients, 17 eyes) of follow-up.

Increase of RI signifies improvement of microcirculation and reduction in the deficit of eye tissue blood supply. Decrease of other rheogram parameters (PMF, IEM) speaks of the better elastic properties of intraocular vessel walls. Upon the whole, the data of transpalpebral rheoophthalmography are indicative of the intraocular hemodynamics improvement and better trophic provision of eye tissues during LILT and upon treatment completion.

At the sixth follow-up month, vision acuity objectively reduced by 0.1–0.2 in 2 patients of group 1 (3 eyes) and in 3 patients of group 2 (4 eyes). The reduction of RI by 0.76 ± 0.36 mOhm and insignificant increase of PMF and IEM (by 0.01 s) were also found to occur. In spite of the changes in vision acuity and ocular hemodynamics,

these parameters continued to exceed in qualitative sense their initial level.

Subjective worsening of the vision organ functional state was not noted. The patients were offered to repeat the LILT course with MACDEL-08 device in complex with general conservative medicamentous treatment.

Thus, achievement of high functional results and the data obtained by transpalpebral rheoophthalmography confirm a positive effect of LILT on vision acuity and parameters of ocular hemodynamics in patients with advanced and far-advanced stages of POAG.

Conclusion. The application of low-intensity laser therapy using HeNe laser-based MACDEL-08 device is a harmless, clinically effective, physiologically justified and technically simple component of the complex treatment of primary open-angle glaucoma. At the same time, insufficient duration of patients follow-up (about 6 months) demands further clinical study of the proposed method of low-intensity laser therapy of this disease.

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