

RESULTS OF SIMULTANEOUS COMBINED LASER TREATMENT OF NEWLY DIAGNOSED PRIMARY OPEN-ANGLE GLAUCOMA

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Today, selection of the optimal treatment method in patients with the early-stage primary open-angle glaucoma (POAG) remains an urgent problem of ophthalmology. There are various approaches to treating such patients, including the use of topical therapy and laser treatments. The study aimed to assess the hypotensive effect and clinical and functional outcomes of the simultaneous combined laser treatment, including YAG-LAT and the subsequent one-time SLT in the same localization zones, in patients with the newly diagnosed early-stage POAG and moderately elevated intraocular pressure (IOP). The study included 100 eyes with stage I POAG, which were divided into two groups: group I — 50 eyes before and after YAG-LAT and SLT; group II — 50 eyes that underwent SLT only. The follow-up period was 12 months. In patients of groups I and II, a decrease in IOP by 28 and 30.5% relative to the baseline IOP was reported at 1 month, and by 32.2 and 32% at 3 months, respectively. The intergroup difference in the extent of IOP decrease at 1 and 3 months was non-significant ($p > 0.05$). There was still good hypotensive effect, up to 29.3% of the preoperative value, 12 months after YAG-LAT and SLT. Twelve months after SLT, the hypotensive effect was 17%. The intergroup difference in the extent of IOP decrease at 12 months was significant ($p < 0.05$). Glaucoma stabilization was reported in groups I and II, but in group II, antihypertensive therapy was required in 63% of cases. The simultaneous combined laser treatment technology (YAG-LAT and SLT) showed a pronounced, persistent hypotensive effect and glaucoma stabilization when used for treatment of the newly diagnosed early-stage POAG.

Keywords: newly identified primary open-angle glaucoma, first-line therapy, selective laser trabeculoplasty, YAG laser activation of the trabecula, alternative drug therapy strategy, hypotensive therapy

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РЕЗУЛЬТАТЫ ОДНОВРЕМЕННОГО КОМБИНИРОВАННОГО ЛАЗЕРНОГО ЛЕЧЕНИЯ ВПЕРВЫЕ ВЫЯВЛЕННОЙ ПЕРВИЧНОЙ ОТКРЫТОУГОЛЬНОЙ ГЛАУКОМЫ

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На сегодняшний день выбор оптимального метода лечения пациентов с начальной стадией первичной открытоугольной глаукомы (ПОУГ) остается актуальной проблемой в офтальмологии. Существуют различные подходы к лечению таких пациентов, среди которых использование местной топической терапии и лазерные методы лечения. Целью работы было провести исследование состояния гипотензивного эффекта и клинико-функциональных результатов одновременного комбинированного лазерного лечения, включающего YAG-ЛАТ и последующую за ней, по тем же зонам локализации, одномоментную СЛТ у пациентов с начальной стадией впервые выявленной ПОУГ с умеренно повышенным уровнем ВГД. В исследование вошли 100 глаз с ПОУГ I стадии, они были разделены на две группы: I группа — 50 глаз до и после проведения YAG-ЛАТ и СЛТ; II группа — 50 глаз, которым была выполнена только СЛТ. Срок наблюдения — 12 месяцев. У пациентов I и II групп через месяц отмечено снижение ВГД на 28 и 30,5%, через 3 месяца на 32,2 и 32% от исходного уровня ВГД соответственно. Различия между группами по степени снижения ВГД через 1 и 3 месяца было статистически незначимым ($p > 0,05$). Через 12 месяцев после YAG-ЛАТ и СЛТ сохранялся хороший гипотензивный эффект, составивший до 29,3% от его дооперационного значения. После СЛТ гипотензивный эффект через 12 месяцев достигал 17%. Различия между группами по степени снижения ВГД через 12 месяцев статистически значимо ($p < 0,05$). В I и II группах наблюдалась стабилизация глаукомного процесса, но во II группе в 63% случаев потребовалась гипотензивная терапия. Технология одновременного комбинированного лазерного лечения (YAG-ЛАТ и СЛТ) показала выраженный, стойкий гипотензивный эффект и стабилизацию глаукомного процесса при лечении начальной стадии впервые выявленной ПОУГ.

Ключевые слова: впервые выявленная первичная открытоугольная глаукома, терапия первой линии, селективная лазерная трабекулопластика, YAG-лазерная активация трабекулы, альтернативная стратегия медикаментозной терапии, гипотензивная терапия

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Glaucoma is a chronic progressive disease of the optic nerve that finally results in irreversible blindness, if left without proper and timely treatment. According to the federal statistical observation data, a total of 1,249,617 glaucoma patients aged over 18 accounting for 1077.8 per 100,000 adult population of the Russian Federation (RF) were registered in 2022 in the RF [1]. The number of glaucoma patients increases annually: 57.5 million people were affected in 2015, their number increased to 65.5 million by the year 2020 [2]. All these data confirm that primary open-angle glaucoma (POAG) is one of the most important socially significant problems all over the world [3]. The early-stage glaucoma has no specific symptoms. Visual acuity usually does not decrease. However, despite this fact, the programmed death of nervous cells and optic nerve fibers is triggered. In this regard, it is necessary to start glaucoma treatment as early as possible, at early stages, to reduce much of the cases of blindness due to glaucomatous optic atrophy [4]. The potential of modern diagnosis methods allows one to detect the slightest glaucomatous alterations in patients. A multicenter scientific-analytical cohort study of 6,407 individuals (12,814 eyes) was conducted in the RF between December 2019 and October 2020, based on the results of which stage I glaucoma was diagnosed in a half of cases in the group with POAG (1995 eyes). This confirms good prospects in the diagnosis and treatment of glaucomatous optic neuropathy (GON) [5]. Therefore, the proper and timely treatment of early-stage glaucoma with the stable hypotensive effect determines the good prognosis in terms of vision for this disorder. According to the Russian (POAG Clinical Guidelines, RF 2024) and foreign regulatory documents, topical drug therapy and selective laser trabeculoplasty can be prescribed as a starter treatment method for early-stage POAG [6]. In the world today, considering the laser technology active development, laser treatment methods are extensively used to treat early-stage POAG. One of the main reasons to switch from hypotensive eyedrops to laser surgery when treating early-stage POAG is low patient compliance with the topical hypotensive therapy due to possible local and systemic side effects [7–9].

The majority of topical hypotensive drugs used to treat glaucoma contain preservatives, which, in turn, negatively affect the condition of the ocular surface and conjunctiva. Considering the fact that glaucoma is a chronic disorder and that treatment with hypotensive eyedrops is lifelong, the long-term use of such drugs lower the efficacy of glaucoma surgery [10]. According to foreign studies, the common cause of intraocular pressure (IOP) decompensation in patients with POAG post filtering surgery is scarring of the artificially created pathways for the intraocular fluid drainage due to the long-term use of the preservative-containing topical hypotensive drugs [11]. The approaches to treatment of early-stage POAG change due to the personalized medicine development. Therefore, in addition to achieving the target IOP it is necessary to consider the influence of treatment on the patient's quality of life. Treatment must be safe, cost-effective, and efficient.

Selective laser trabeculoplasty (SLT) is successfully used as a first choice intervention. This is a more cost-effective treatment option for POAG, than drug therapy [12]. SLT is recommended by the European Glaucoma Society and the World Glaucoma Association as first-line therapy for glaucoma. This is due to the fact that it helps stabilize IOP in a few years without using topical hypotensive therapy, thereby increasing patient compliance with treatment. The patient stops experiencing side effects of topical hypotensive drugs, and no monthly financial costs are required, so SLT is a cost-effective method to treat glaucoma [13, 14]. According to the Russian

literature, the studies focused on the SLT efficacy when used as first-line therapy showed that the hypotensive effect of this laser surgical procedure was not durable enough, it accounted for 11–20% of the baseline IOP by month 12 of follow-up [15, 16]. Due to this fact the new combination laser technologies having a more pronounced hypotensive effect have started appearing in Russia.

A combination laser technology using different mechanisms of affecting the trabecular mesh (YAG laser activation of the trabecula and SLT), which complement each other based on the mechanism of action and ensure the more pronounced persistent hypotensive effect at various glaucoma stages, was developed and patented in 2024 at the glaucoma diagnosis and treatment department of the Yekaterinburg Eye Microsurgery Center [17]. According to the authors, the YAG-LAT + SLT technique developed ensured the glaucomatous process stabilization through achieving the necessary target intracranial pressure (ICP) depending on the glaucoma stage [18].

We found no data on the simultaneous use of combination laser techniques for treatment of the newly diagnosed POAG before hypotensive therapy prescription in the literature.

The study aimed to assess the hypotensive effect and clinical and functional outcomes of the simultaneous combination laser treatment, including YAG laser activation of the trabecula (YAG-LAT) and the subsequent one-time selective laser trabeculoplasty (SLT) in the same localization zones, in patients with the newly diagnosed early-stage POAG and moderately elevated IOP.

METHODS

Clinical assessment was based on evaluation of the clinical and functional state of 100 patients (100 eyes) with the newly diagnosed early-stage POAG aged 37–83 years. The nonrandomized prospective clinical and functional analysis of treatment outcomes in these patients was conducted. The gender distribution was as follows: 38 males (38%) and 62 females (62%). The follow-up period was 12 months.

Patients were divided into two groups. Group I included 50 patients (50 eyes), who underwent simultaneous YAG-LAT and SLT. The gender distribution was as follows: 30 females (60%) and 20 males (40%). The patients' age was 37–80 years.

Group II included 50 patients (50 eyes), who underwent SLT only. The gender distribution was as follows: 32 females (64%) and 18 males (36%). The patients' age was 38–83 years. The gender and age differences between groups of patients were non-significant.

Inclusion criteria: newly diagnosed stage I POAG (before prescription of hypotensive eyedrops) with the moderately increased IOP (Po, 22–28 mmHg), II–III degree of pigmentation on the anterior chamber angle.

Exclusion criteria: bullous keratopathy, high IOP (Po, ≥ 29 mmHg), corrected visual acuity less than 0.4; reduced transparency of optical media that interfere with the computed perimetry, poor computed perimetry quality (fixation loss > 25%, false positives and false negatives > 25%); high refractive errors; central retinal dystrophy.

Monitoring of the clinical and functional analysis in patients with the newly diagnosed POAG was performed before using the combination laser technique, as well as 1, 3, 6, and 12 months after laser treatment.

The clinical and functional analysis of patients with the newly diagnosed POAG conducted at all the follow-up terms specified included the following: visometry, gonioscopy, slit lamp examination, induction-based tonometry with the

Table 1. Mean values of clinical and functional parameters in groups I and II before laser surgery, $M \pm \sigma$

Parameter	Group I	Group II	<i>p</i>
BCVA	0.8 ± 0.1	0.8 ± 0.2	> 0.05
IOP, mmHg	26.0 ± 1.7	26.3 ± 1.5	> 0.05
MD, dB	2.6 ± 1.5	2.4 ± 1.7	> 0.05
sLV, dB	3.7 ± 1.9	3.0 ± 1.5	> 0.05
Average RNFL, μm	98.0 ± 5.2	100.5 ± 4.9	> 0.05
Average GCC, μm	90.0 ± 4.2	92.0 ± 4.8	> 0.05

Note: BCVA — best-corrected visual acuity; RNFL — retinal nerve fiber layer.

use of the iCare TA01i tonometer (Icare Finland Oy, Finland), indirect ophthalmoscopy. The IOP values measured using the iCare tonometer were considered as “true” IOP (P_o), since this tonometry type has a slight effect on the eye’s fibrous membrane.

To accurately diagnose early-stage POAG, the optical coherence tomography (RTVue 100 system, Optovue, USA) data were used, i.e. the retinal nerve fiber layer and ganglion cell complex thickness, optic nerve head profile, along with the unconventional computed perimetry methods (Octopus 600 system, Haag-Streit Diagnostics, Switzerland). The PULSAR perimetry was used to diagnose the visual field, since this method was developed specifically for early detection of glaucoma; it showed sensitivity and specificity, when used to detect early-stage glaucoma [19]. When using computed perimetry, the G pattern and dynamic strategy were used. The G pattern is characterized by high density of test points in the paracentral zone for increasing the likelihood of detecting the paraconcomitant optic neuropathy (GON) early signs.

Patients of group I underwent combination treatment (YAG-LAT and SLT) as follows.

At first, in phase I, the Visulas YAG-3 Nd:YAG laser (wavelength 1064 nm) (Carl Zeiss Meditec Inc., Germany) was used to perform YAG-LAT in the lower part of the anterior chamber angle (180 degrees) via application of 50–60 single pulses with the energy of 0.9–1.0 mJ at equal distances from one another; the spot diameter was 8–10 μm , and the laser exposure time was 3 ns [20].

Then, in phase II, we switched to the Ellex Solo Nd:YAG laser (Ellex Medical Pty Ltd., Australia) with frequency doubling (532 nm) to perform SLT in the same zone of the lower part of the anterior chamber angle (180 degrees) with 70–75 non-overlapping laser applications with the energy of 0.5–0.6 mJ; the spot diameter was 400 μm , and the laser exposure time was 3 ns.

Patients of group II received only SLT performed using the doubled-frequency (532 nm) Ellex Solo Nd:YAG laser (Ellex Medical Pty Ltd., Australia); the spot diameter was 400 μm , and the laser exposure time was 3 ns; 70–80 non-overlapping laser applications with the energy of 0.7–0.9 mJ were used in the lower part of the anterior chamber angle (180 degrees).

In the postoperative period, patients of group I, who received simultaneous combination laser treatment, were prescribed instillation of nonsteroidal anti-inflammatory drugs for 7 days (bromfenac 0.09%, 1 drop once a day); topical hypotensive therapy was not prescribed.

After receiving SLT only (group II), no anti-inflammatory agent instillation or topical hypotensive therapy was prescribed.

According to the preoperative assessment data, the average baseline IOP was 26.1 ± 1.7 mmHg in patients of group I without local hypotensive therapy, while in patients of group II without topical hypotensive therapy it was 26.3 ± 1.5 mmHg; the intergroup difference is also non-significant ($p > 0.05$).

Mean clinical and functional parameter values in patients of groups I and II before laser surgery are provided in Table 1.

Statistical analysis of the results was conducted using STATISTICA 10.0 and Excel 2020. The data obtained were processed using variation statistics with normal distribution determined using the Shapiro–Wilk test. The data are presented as the mean (M) and standard deviation (σ), ($M \pm \sigma$). Student’s t -test was used to compare mean values and assess significance of differences. The differences were considered significant at $p < 0.05$. Significance of differences between identical indicators was calculated using the Mann–Whitney U -test; significance of differences between the indicators reported before and after treatment within the same group was calculated using the Wilcoxon test.

RESULTS

The IOP decreased by 28% of the baseline a month after using the combination laser treatment involving YAG-LAT and SLT (group I); at 3 months it decreased by 32.2% of the baseline IOP. In patients, who received SLT only (group II), the IOP decrease relative to baseline was 30.5% within a month and 32% within 3 months. The difference in the extent of IOP decrease reported within a month and 3 months between groups I and II was non-significant ($p > 0.05$).

There was still persistent hypotensive effect that accounted for 29.3% of the preoperative value 12 months after the simultaneous combination laser treatment involving YAG-LAT and SLT. There was no persistent hypotensive effect in the long term after SLT (within 12 months), and the IOP decrease relative to baseline was 17%. The differences in the extent of IOP decrease relative to baseline between groups I and II were significant ($p < 0.05$) in the long term (within 12 months).

The IOP values (P_o , mmHg) reported at various follow-up terms are provided in Table 2.

In the long term (within 12 months) after the simultaneous combination laser treatment (YAG-LAT + SLT), the target IOP was achieved in 82% of cases (41 eyes out of 50); in 18% of cases (9 eyes out of 50), normal IOP was achieved by prescribing topical hypotensive therapy (latanoprost 0.005% once daily). In a year, in patients post SLT only, the target IOP was achieved in 37% of cases (18 eyes out of 50), while in 63% of cases (32 eyes out of 50) there was a need for prescription of topical hypotensive therapy (latanoprost 0.005% once daily). The target IOP values were determined by the Russian regulatory documents (POAG Clinical Guidelines, RF 2024): P_o 16–18 mmHg. The slit lamp examination of individuals in groups I and II revealed dystrophic changes in the anterior segment of the eye, exogenous pigmentation and pseudo-exfoliation of the iris and lens. Gonioscopy showed that the anterior chamber angle was of medium width or wide, open, with the II–III degree of pigmentation. Ophthalmoscopy showed that individuals in groups I and II had the pale pink optic disc with clear margins;

Table 2. Mean IOP, Po (mmHg), at various follow-up terms, $M \pm \sigma$

Group	Before surgery	After surgery			
		1 month	3 months	6 months	12 months
I ($n = 50$)	26.1 \pm 1.7	18.8 \pm 2.1	17.7 \pm 1.9	18.8 \pm 2.5	18.7 \pm 2.6
II ($n = 50$)	26.3 \pm 1.5	18.3 \pm 2.9	17.9 \pm 1.5	20.5 \pm 2.8	21.9 \pm 2.5
p	> 0.05	> 0.05	> 0.05	< 0.05	< 0.05

in the central retinal area, foveal and macular reflexes were preserved, no abnormalities were revealed.

During the 12-month follow-up all patients of group I (50 eyes) showed stabilization of visual functions and glaucomatous process; the glaucomatous process stabilization was also reported in all patients of group II (50 eyes), but in this group it was achieved by prescribing topical hypotensive eyedrops, which were necessary in 63% of cases (31 eyes). The glaucomatous process stabilization in patients with early-stage glaucoma was confirmed by computed perimetry and optical coherence tomography (OCT) of the optic disc and retinal ganglion cells. The difference in this parameter reported for patients of groups I and II by the end of follow-up (after 12 months) was non-significant ($p > 0.05$).

The dynamic changes of the average clinical and functional parameter values in patients of groups I and II before laser surgery and after 12 months are provided in Table 3.

In the early postoperative period, 10% of patients with early-stage POAG and moderately increased IOP post simultaneous combination laser treatment (group I, 5 eyes) reported eye redness and light sensitivity; the slit lamp examination revealed conjunctival injection without any signs of inflammation in the anterior chamber. All the above symptoms disappeared during topical anti-inflammatory treatment in the form of bromfenac 0.09% eyedrops once daily for 7 days.

As for patients with early-stage POAG post SLT (group II), in the early postoperative period 14% (7 eyes) showed the reactive IOP increase, which recovered spontaneously without hypotensive therapy prescription; in 16% of cases (8 eyes), inflammatory eye injection occurred, which was jugulated by topical steroid anti-inflammatory therapy in the form of dexamethasone 0,1% eyedrops 3 times daily for 7 days.

DISCUSSION

In contrast to the use of SLT only, the simultaneous combination laser surgery technique (YAG-LAT and SLT) used for treatment of patients with the newly diagnosed early-stage POAG makes it possible to achieve the more pronounced persistent hypotensive effect of surgery within 12 months (up to 29.3% of baseline IOP within a year after laser surgery). The fact of achieving the target IOP (Po 16–18 mmHg) was reported in 82% of patients in group I, who received no topical hypotensive therapy. In a comparative aspect with group II of patients, who received SLT only, the IOP decrease within a year accounted for 17% of baseline IOP values, and the target IOP (Po 16–18 mmHg) was achieved only in 37% of patients with the newly diagnosed early-stage POAG. In group II, the extent of IOP decrease within 6–12 months is comparable with the Russian literature data on the efficacy of SLT as first-line therapy for glaucoma. Thus, it was shown in 2014 that the extent of IOP decrease within 12 months after using SLT as first-line therapy was about 20% [15]; similar data were obtained by other researchers [20].

There is a causal relationship between the laser exposure mechanism and the pronounced persistent hypotensive effect when using the simultaneous combination laser treatment. The simultaneous combination laser treatment (YAG-LAT and SLT) involves various mechanisms. In the first phase, when performing YAG laser activation of the trabecula, the main mechanism underlying the effect is related to the micro-hydraulic shock wave generated by laser energy and directed at the trabecula. On the one hand, the wave fragments biomaterial in the trabecular zone (primarily pigment) that impairs drainage and moves biomaterial deeper into the trabecular mesh lumens.

Table 3. Dynamic changes of the average clinical and functional parameter values in patients of groups I and II before laser surgery and after 12 months, $M \pm \sigma$

Parameter	Before laser surgery	After 12 months	p
	Group I		
BCVA	0.8 \pm 0.1	0.8 \pm 0.1	> 0.05**
MD, dB	2.6 \pm 1.5	2.72 \pm 1.4	> 0.05**
sLV, dB	3.7 \pm 1.9	3.6 \pm 1.7	> 0.05**
Average RNFL, μ m	98.0 \pm 5.2	101.0 \pm 4.6	> 0.05**
Average GCC, μ m	90.0 \pm 4.2	92.0 \pm 3.8	> 0.05**
Group II			
BCVA	0.8 \pm 0.2	0.8 \pm 0.1	> 0.05**
MD, dB	2.4 \pm 1.7	2.5 \pm 1.5	> 0.05**
sLV, dB	3.0 \pm 1.5	3.2 \pm 1.3	> 0.05**
Average RNFL, μ m	100.5 \pm 4.9	100.9 \pm 5.1	> 0.05**
Average GCC, μ m	92.0 \pm 4.8	92.9 \pm 4.2	> 0.05**
p	> 0.05*	> 0.05*	

Note: * — $p > 0.05$, the difference between indicators in two groups; ** — $p > 0.05$, difference between pre-treatment and post-treatment values within a group.

On the one hand, it stretches the trabecula, which results in expansion of the intertrabecular spaces. This, in turn, further increases their permeability for biomaterial particles, improving the overall trabecular permeability.

In the second phase of the simultaneous combination laser treatment, the same localization zones simultaneously undergo SLT, the main mechanism of which is aimed at photothermolysis [21]. At the same time, the conditions for photothermolysis are significantly improved due to the fact that the microhydraulic shock wave breaks down the biomaterial after YAG-LAT, freeing access to the trabecular surface, and also promotes its more compact and uniform movement into the trabecular mesh. This contributes to more accurate focusing, concentration, and

distribution of the necessary laser energy across the depth of the mesh intratrabecular spaces on the photothermolysis objects, increasing the SLT procedure efficacy.

CONCLUSIONS

The simultaneous combination laser treatment technique (YAG-LAT combined with SLT) proposed as first-line therapy showed the pronounced stable hypotensive effect throughout the follow-up period when used for treatment of the newly diagnosed early-stage POAG. Furthermore, the patients showed stabilization of visual functions and glaucoma manifestations.

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