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Nd:YAG laser goniopuncture as a mandatory adjuvant procedure after non-penetrating deep sclerectomy (long-term observation results)

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Today, Nd:YAG laser goniopuncture (LGP) is considered a mandatory non-penetrating deep sclerectomy adjuvant procedure. However, its indications and timing remain debatable. **Purpose** — to evaluate the effect of Nd:YAG laser goniopuncture on the long-term hypotensive effectiveness of non-penetrating deep sclerectomy. **Material and methods.** The study included 114 patients after non-penetrating deep sclerectomy (NPDS). In the control group (n=58), Nd:YAG laser goniopuncture was performed within 3.4±1.9 (1.5—6.7) months, and in the main group (n=56) — within 1.12±0.08 (0.9—1.5) months after the surgery. Ultrasound biomicroscopy (UBM) was used to evaluate the semiotics of trabecular-Descemet's membrane (TDM), intrascleral canal (ISC) and filtering bleb. The follow-up period was 5 years. **Results.** According to UBM data, the thickness (0.10±0.009 mm) and density (50±6%) of TDM (p=0.0001) increased before LGP in the control group, the height of ISC decreased to 0.49±0.19 (0.20—0.40) (p=0.03), the height of UBM scan — to 1.49±0.05 (1.41—2.9) (p=0.0001); IOP (P_0) was 18.48±4.7 (11.2—22.9) mmHg (p=0.001). In the main group before LGP, TDM thickness was 0.08±0.006 mm, density was 40±5%, and IOP (P_0) was 15.7±4.1 (9.1—18.5) mm Hg. Complete hypotensive success was achieved in 83.6% of cases in the control group and 96.2% in the main group in 6 months; 68.07% and 92.59% in 12 months; 41.3% and 75.8% in 24 months; 15.25% and 48.93% in 36; 15% and 34.8% in 60 months after the surgery, respectively (p=0.0001, 95% confidence interval). **Conclusion.** TDM is an additional level of retention of aqueous humor and plays key role in the formation of outflow pathways after NPDS. Performing LGP in the early postoperative period is an effective and safe adjuvant option, which excludes the influence of TDM on the formation of aqueous humor outflow pathways and significantly increases the long-term hypotensive efficacy of non-penetrating deep sclerectomy.

Keywords: primary open angle glaucoma, glaucoma surgery, non-penetrating deep sclerectomy, trabecular Descemet membrane, Nd:YAG laser goniopuncture

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In the recent decades, non-penetrating deep sclerectomy (NPDS) has been used extensively as an initial surgical procedure in patients with primary open-angle glaucoma (POAG). Similarly to trabeculectomy (TE), NPDS forces intraocular fluid (IOF, aqueous humor) to flow out into the intrascleral canal (ISC) and further into the filtering bleb (FB), making both NPDS and TE a type of "bleb-depended" filtering procedures (i.e. they depend on the presence and condition of FB) [1—4]. In order to improve hypotensive efficiency on the level of ISC and FB, NPDS — same as TE — employs adjuvants: 5-fluorouracil, mitomycin C, bevacizumab, drainage systems and viscoelastics, laser suturolysis and/or needling-revision [1, 5—8]. However, the hypotensive effect of NPDS still lasts less, compared to penetrating surgeries [1, 2, 9, 10]. According to some studies, additional level of IOF retention in NPDS can be achieved with semi-permeable trabecular-Descemet's membrane (TDM) due to individually determined density, natural fibrosis, vascularization and "clogging" by pigment, as well as blockade by the iris root (radix iridis) [7, 11—13]. Consequently, the success of NPDS depends equally on the condition of subscleral and subconjunctival parts of the IOF outflow, and the filtering capabilities of TDM. The only procedure that can stimulate the activity of TDM is Nd:YAG-laser goniopuncture (LGP). However, the criteria for its functional condition remain undetermined, making the questions of the necessity, indications, frequency, timing and technique of Nd:YAG LGP relevant.

Purpose of the study — to evaluate the objective criteria for the functional condition of TDM and the impact of Nd:YAG LGP on the long-term hypotensive effects of NPDS.

Material and methods

The study included 114 patients (114 eyes) after non-penetrating deep sclerectomy (NPDS). **Table 1** shows their characteristics.

The groups were relevant by gender, age, glaucoma stage, and amount of local drug therapy (LDT). Inclusion criteria were absence of intraoperative perforation of TDM, hemorrhagic complications or clinically significant ciliochoroidal detachment (CCD) in the early postoperative period. Exclusion criteria were uveitis, trauma, previous surgeries, as well as conjunctival scarring of any etiology in patient's history. The patients were followed up for 5 years. All of them underwent NPDS as the first surgical procedure. Surgeries did not differ in nuances from standard method suggested by S.N. Fyodorov and V.I. Ko-

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***Table 1*. Characteristics of the study patients**

Indicator	Group 1 (control group)	Group 2 (main study group)	*p*
Number of eyes	58	56	
Age, year	56,62±12,23	54,71±14,24	
Males/females	21/37	18/38	
Ethnicity:			
caucasian	51	48	
mongoloid	7	8	
Glaucoma form and type:			
Primary open-angle	12	15	
pseudo-exfoliative	43	39	
pigmentary	03	02	
preoperative IOP level, mm Hg	24,3±4,5	21,9±4,1	0,05
preoperative LDT amount	2,3±0,9	2,4±0,1	
Comorbid ophthalmic pathologies:			
Cataract	12	14	
age-related macular degeneration	4	2	
myopic chorioretinal dystrophy	1	1	
dry eye syndrome	7	9	
Previous laser or surgical interventions	0	0	
Stage:			
initial, absolute (%)	10 (16,4%)	8 (14,8%)	
developed, absolute (%)	33 (56,6%)	39 (69,6%)	
extensive, absolute (%)	15 (12,2%)	9 (15,6%)	

Note. LDT – local drug therapy.

zlov in 1984 [14]. In all cases, FB was formed as the dome basis, and the surgery was finished by injecting metabolic antagonist (0.1 ml of 0.1% 5-fluorouracil solution) and corticosteroid (0.3 ml of dexamethasone solution) under the conjunctiva into the FB area. Standard postoperative drug therapy included local application of antibiotic (0.5% solution of levofloxacin 4 times per day for 10–14 days), corticosteroid (0.1% solution of dexamethasone for 4 weeks) and nonsteroidal anti-inflammatory drug (NSIAD) 0.09% Bromfenacum, which was prescribed simultaneously with the steroidal agent or changed to as a part of the extended anti-inflammatory regimen. During the second stage, Nd:YAG LGP was performed in the absolute number of cases. In the first group (retrospective part of the study), time of LGP was determined as the moment of patient's attendance and amounted to 3.45±1.9 (1.5–6.7) months, while IOP (R_0) was 18.48±4.7 (11.2–22.9) mm Hg. In the second group (prospective part of the study), LGP was performed as a preventative measure, which was dictated by the intention to exclude the influence of TDM on further formation of IOF outflow pathways in the set period of 1.12±0.08 (0.9–1.5) months after the surgery. LGP was performed when R_0 was no lower than 13 mm Hg, which according to previously conducted studies is the IOP level that is the safest for performing the laser stage of the surgery [15]. With R_0 lower than 11 mm Hg, patients underwent B-scan and ultrabiomicroscopy (UBM) to exclude CCD. LGP was performed using YAG-laser of 1064 nm wavelength with Magna Gonio Laser Lens (U.S.A.) using single laser pulses technique. Laser power was 3.3±1.2 (1.6 to 5.0) mJ depending on the density of TDM, mean amount of impulses – 8±2.9 (5 to 12), 2–3 pulses per flash. The central semi-transparent area of TDM associated with presence of intrascleral cavity was considered as the preferable location for LGP. Before the surgery, all patients had 1% solution of pilocarpine instilled in order to immobilize the iris root (radix iridis) as much as possible.

In addition, the correct orientation of the laser pulses excluded the damaging effect of the ciliary body, and also minimized the possibility of occlusion of the TDM "window" by the iris root in the case of anterior chamber angle having low profile. In case of a threat of TDM blockade by the iris root, prophylactic local gonioplasty (coagulating laser with a wavelength of 532 nm) was performed. Its hole (microfistula) being "visible", as well as FB being extended to the external compression of the eyeball, were considered signs of functional consistency of TDM. Based on the purpose of the study, all patients underwent UBM within 3 days, as well as before and after Nd:YAG-LGP. Using UBM, the height (in mm), the thickness (in mm) and the acoustic density (in %) of the TDM, the height of the ISC (in mm), and the parametric index of the scan height (in mm) were evaluated. For the biomicroscopic characterization of FB, Murfield Evaluation Scale was used to determine its height, area and degree of vascularization [16]. According to indications (narrowing of the intrascleral lake and/or lowering of the scan height, cicatricial transformations of FB), rehabilitation measures were carried out after the laser stage

[17]. The IOP level was evaluated at 3 days, before and after LGP, as well as at 6, 12, 24, 36, 48 and 60 months after surgery. The success of the surgical procedure was interpreted in accordance with the World Glaucoma Association (WGA) consensus [18]. The upper limit of "complete" hypotensive success (without additional antihypertensive therapy throughout the observation period) was considered to be a level of P_0 equal to or less than 15 mm Hg. Cases of local drug therapy (LDT) restart or reoperation were considered a failure (IOP decompensation due to insolvency of the IOF outflow pathway confirmed by UBM). Descriptive statistics was used for both numerical and categorical data. Kaplan-Meyer survival curves were used to evaluate the long-term hypotensive results and intergroup differences (depending on the timing of LGP). The difference between the curves was checked using the Gehan-Wilcoxon, Cox-Mantel, and log-rank criteria. Continuous variables were calculated using Student's t-test. Z-criterion was used for comparative assessment of the IOP differences between the groups according to the criterion of complete success, qualified (additional purpose of LDT), or failure (reoperation). Statistical analysis was performed using SPP Statistica 8.0 (Stat Soft Inc., USA), a confidence level of less than 0.05 was considered significant. The presentation of the data follows the guidelines proposed by Jabs for a series of clinical cases and supported by the WGA consensus group. All studies were conducted in accordance with the ethical standards of the Helsinki Declaration for scientific research.

Results

In both groups, P_0 level was 9.84±2.37 mm Hg on the 3–7 days after surgery (6–13), while during the early postoperative period it was identical to the minimal number of complications **(table 2)**.

As seen in **table 2**, the time of performing LGP in the groups was associated with various parameters of laser impulses. In the 1st group, mean laser energy during LGP was 3.85±0.9 (2.7–5.0) mJ, in the 2nd group it was 1.95±0.6 (1.6–2.3) mJ (p=0.0001); mean number of pulses – 9.2±1.6 (8–12) and 6.0±1.6 (5–7), respectively (p=0.0001). The **table 2** shows that the most common complication after LGP was CCD. It was diagnosed in 8.6% of cases in the 1st group and in 3.5% of cases in the 2nd group (p=0.00001).

According to UBM, on the third day after surgery the height of internal fistula in both groups was 0.95±0.09 mm, its thickness – 0.05±0.09 mm, acoustic density – 40±5%, the height of ISC (mm) and scan height (mm) did not differ significantly between the groups **(table 3)**.

Before LGP group 1 showed an increase in the thickness (0.10±0.009 mm) and density (50±6%) of TDM (*p*=0.0001), a decrease in ISC height (mm) by 0.49±0.19 (0.20-0.40) (*p*=0.03), scan height (mm) by 1.49±0.05 (1.41-2.9) (*p*=0.0001). In group 2, the thickness and density of TDM, the ISC height (mm) and scan height (mm) by the time of LGP did not change compared to the initial values. The IOP level in the 1st group by the time of LGP was 18.48±4.7 (11.2-22.9) mm Hg, was significantly higher than in group 2 (*p*=0.001), and was associated with changes in the semiotics of TDM according to UBM data. On the other hand, earlier performance of Nd:YAG-LGP was accompanied by a significant increase in ISC height (mm) – 0.57±0.21 (0.39-0.6) (*p*=0.0001) and scan height (mm) – 2.1±0.64 (1.46–2.74) (*p*=0.0001), which attested to the "plasticity" of tissues and the ability to self-remodeling of the IOF outflow tract in the early postoperative period after NPDS **(Fig. 1)**. In addition, it should be noted

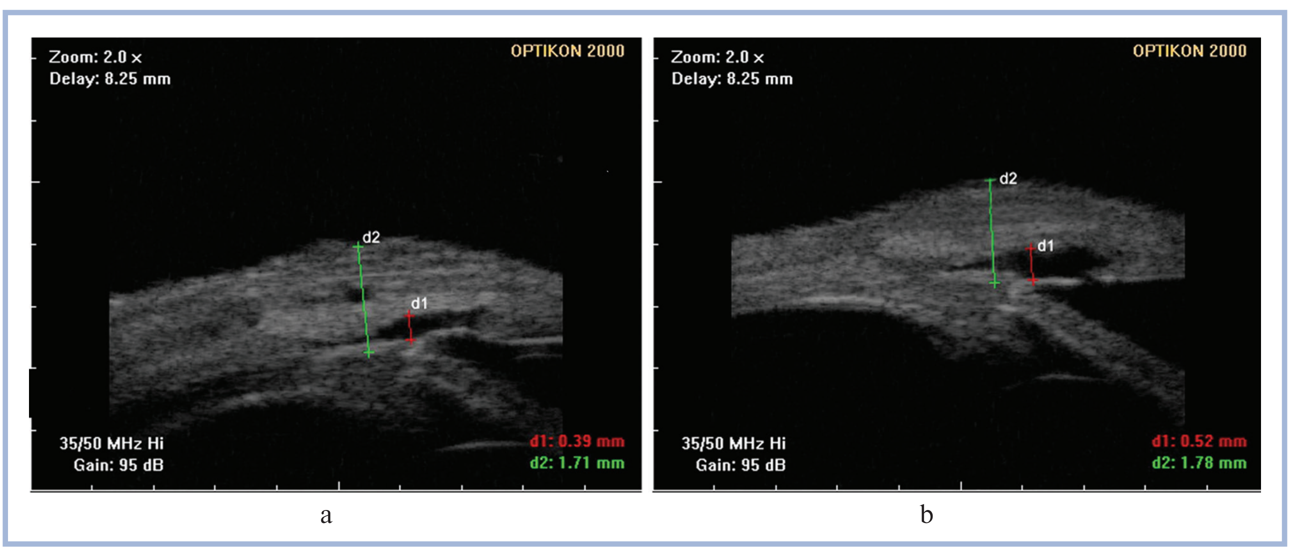

Fig. 1. **Ultrasound biomicroscopy of the aqueous humor outflow pathways after non-penetrating deep sclerectomy.**

d_1 — intrascleral height (mm); d_2 — scan height (mm); a — aqueous humor outflow pathways at day 3 after NPDS, d_1 — 0.39 mm, d_2 — 1.71 mm; b — aqueous humor outflow pathways at day 16 after NPDS and Nd:YAG LGP. Increase in the intrascleral height (d_1 — 0.52 mm) and scan height (d_2 — 1.78 mm) can be observed.

Table 2. **Perioperative characteristics, complications and postoperative manipulations**

Indicator	Group 1 (control group)	Group 2 (main study group)	p
Complications (intraoperative and during first 3—7 days):			
intraoperative perforation of TDM	—	—	
shallow anterior chamber, absolute (%)	1 (1,7%)	—	
external filtration, absolute (%)	1 (1,7%)	—	
hyphema (trace), absolute (%)	2 (3,5%)	1 (1,7%)	
CCD (sublinical), absolute (%)	1 (1,7%)	—	
malignant glaucoma	—	—	
TDM blocked by iris root, absolute (%)	1 (1,7%)	1 (1,7%)	
Nd:YAG-LGP time of operation, months	3,46±1,9 (1,5—6,7)	1,12±0,08 (0,9—1,5)	0,0001
P0 before Nd:YAG-LGP, mm Hg	18,48±4,7 (11,2—22,9)	15,7±4,1 (9,1—18,5)	0,001
pulse energy, mJ	3,85±0,9 (2,7—5,0)	1,95±0,6 (1,6—2,3)	0,0001
number of pulses	9,2±1,6 (8—12)	6,0±1,6 (5—7)	0,0001
laser gonioplasty, absolute (%)	12 (20,6%)	9 (16,1%)	0,7
Complications after Nd:YAG-LGP:			
hypotony w/o CCD, absolute (%)	1 (1,7%)	1 (1,7%)	
hypotony with CCD, absolute (%)	5 (8,6%)	2 (3,5%)	0,0001
hyphema, absolute (%)	1 (1,7%)	1 (1,7%)	
Occlusion of TDM by iris:			
during LGP	—	—	
after LGP, absolute (%)	1 (1,7%)	1 (1,7%)	
damaged FB, absolute (%)	1 (1,7%)	—	
Surgical interventions after NPDS and Nd:YAG-LGP:			
subconjunctival injections of 5- fluorouracil (3 to 5), absolute (%)	28 (48,3%)	14 (25%)	0,02
needling-revision (2 to 6 procedures), absolute (%)	31 (53,4%)	18 (32,1%)	0,03
laser suturolysis, absolute (%)	9 (15,5%)	5 (8,92%)	0,03

Table 3. **UBM-semiotics of TDM, intrascleral canal and scan height**

Indicator	Time					
	3rd day		before LGP		after LGP	
	1st group	2nd group	1st group	2nd group	1st group	2nd group
TDM height, mm	0,952±0,07 (0,80—1,1)	0,947±0,09 (0,79—1,2) p_{1-2}=0,7	0,952±0,07 (0,80—1,1)	0,947±0,09 (0,79—1,2) p_{1-2}=0,7	0,952±0,07 (0,0—1,1)	0,947±0,09 (0,79—1,2) p_{1-2}=0,7
TDM thickness, mm	0,07±0,006 (0,05—0,09)	0,07±0,002 (0,05—0,09) p_{1-2}=0,7	0,10±0,009 (0,07—0,11)	0,08±0,006 (0,06—0,094) p_{1-2}=0,0001	—	—
TDM density, %	40±5 (35—45)	40±5 (35—45) p_{1-2}=1,0	50±6 (49—56)	40±5 (35—45) p_{1-2}=0,0001	—	—
ISC height, mm	0,55±0,05 (0,28—0,40)	0,56±0,01 (0,3—0,42) p_{1-2}=0,1	0,49±0,19 (0,20—0,40)	0,56±0,15 (0,3—0,42) p_{1-2}=0,03	0,44±0,01 (0,28—0,55)	0,57±0,21 (0,39—0,6) p_{1-2}=0,0001
Scan height, mm	1,62±0,05 (1,49—2,9)	1,61±0,03 (1,50—2,9) p_{1-2}=0,2	1,49±0,05 (1,41—2,9)	1,63±0,05 (1,50—3,1) p_{1-2}=0,0001	1,57±0,74 (0,83—2,21)	2,1±0,64 (1,46—2,74) p_{1-2}=0,0001

Note. p_{1-2} – significance in the 1st and 2nd groups.

that later times of performing LGP in the 1st group were accompanied by a large number of needling procedures (p=0.03) and 5-fluorouracil injections into the FB area (p=0.02) in the postoperative period **(see. Table 2)**. The "complete" hypotensive success in the groups, depending on the timing of Nd:YAG-LHP according to the Kaplan-Meier survival curves was 83.6% (95% CI, 82.4–99.8%) in the control group and 96,2% (95% CI, 86.8–99.7%) in the main (clinical) group in the first 6 months after surgery; 68.07% (95% CI, 64.8–80.4%) and 92.59% (95% CI, 80.5–95.4%) after 12 months; 40.7% (95% CI, 26.8–59.7%) and 75.8% (95% CI, 70.8–89.7%) after 24 months; 15.2% (95% CI, 10.8–29.7%) and 48.93% (95% CI, 36.8–59.7%) after 36, 48 and 60 months, respectively **(Fig. 2)**. The median of survival in the 1st group was at 20 months, in the 2nd group – at 35 months after surgery (p=0.001).

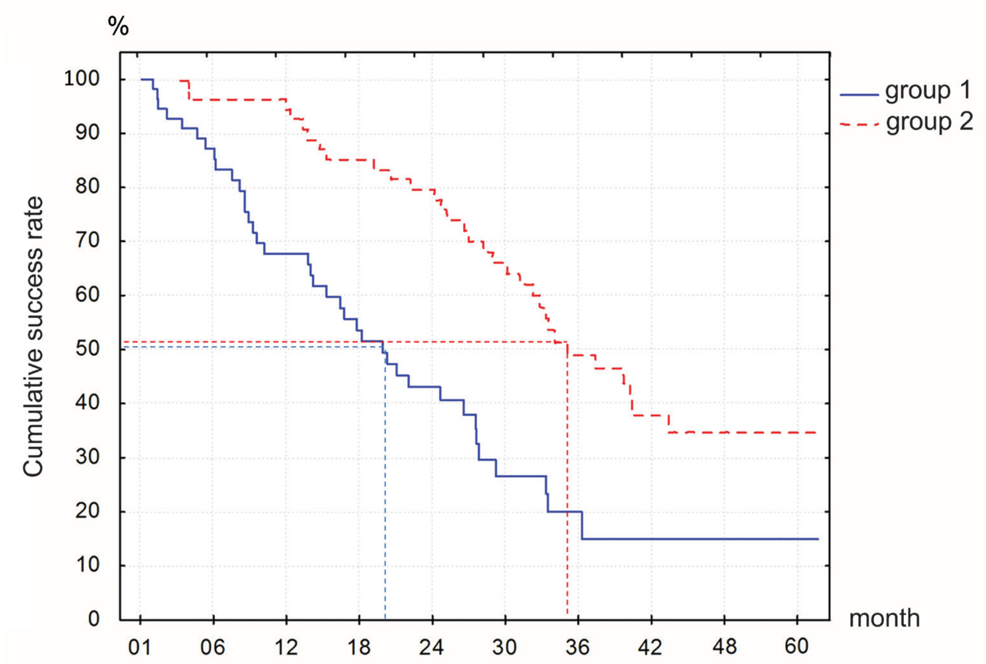

Fig. 2. **Kaplan-Meyer curves of hypotensive effect.**

Kaplan-Meier curve changes after NPDS and Nd:YAG LGP during the 60-months follow-up. Difference between the curves of full hypotensive success is significant (p=0.001).

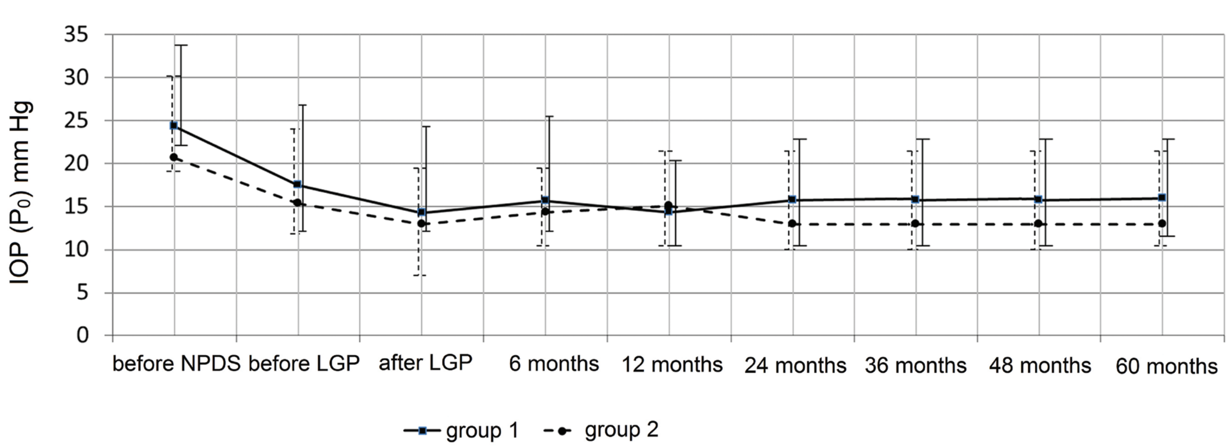

Fig. 3. **Mean IOP values during the follow-up, only «complete success» results after NPDS and Nd:YAG LGP.**

The differences between the survival curves were significant according to the Gehan-Wilcoxon test (p=0.00004), Cox-Mantel test (p=0.00005) and the log-rank test (p=0.0002). In patients with "complete" hypotensive success, the P_0 level, according to the univariate t-test, was 15.6±4.6 mm Hg in group 1, in group 2 – 15.7±4.3 mm Hg after 12 months, 16.7±4.35 and 14.9±1.6 mm Hg after 24 months (p=0.004), 16.8±3.99 and 14.5±3.2 mm Hg, respectively – after 60 months (p=0.0001) after surgery **(Fig. 3)**. In the case of "qualified success", the patients were re-prescribed LDT to achieve the target pressure, with the average number of drugs being 2.1±0.5 in both groups. Decompensation of IOP on LDT was an indication for reoperation.

Discussion

UBM monitoring of the IOF outflow tract revealed significant changes in the morphology of TDM (density and thickness) at 3.46±1.9 (1.5-6.7) months after surgery, which was accompanied by higher IOP values, a significant decrease in ISC height (mm) and scan height (mm). This is consistent with previously obtained data on scleral lake obliteration and on the "loss" of FB in the absence of Nd:YAG LGP within 3–6 months after surgery [4]. N. Anand and R. Pilling [11] speak of an increase in IOF outflow resistance in the "window" of TDM, which is certainly accompanied by progressive subconjunctival fibrosis. J. Goldsmith and I. Ahmed associate the filtering ability of TDM with the presence and size of the scleral lake as a key factor in the success of the NPDS, and recommend performing LGP as early as 6–8 weeks after surgery [19]. A number of sources indicate the advisability of performing LGP only in the presence of ISC, and its fibrosis and disappearance are considered a contraindication to performing goniopuncture [19-22]. S. Al Obiedan [12] notes that with insufficient filtering capacity of TDM, the IOP level always increases, which requires mandatory performance of Nd:YAG LGP. However, according to literature, there is no systematic approach to the timing and frequency of LGP after NPDS. The frequency of LGP varies from 4.7 to 63.0%, and its timing from 6–8 weeks to several years after surgery. At the same time, it remains unclear whether the Nd:YAG LGP is considered a mandatory or optional stage of non-penetrating surgery. One of the first mentions of NPDS as a two-stage procedure was the experimental study by T. Hara [23], when the second stage (several days after the operation) involved breaking the trabecula remnants with Nd:YAG laser. Zsolt Varga and Tarek Shaarawy [1] also spoke about increasing the effectiveness of the NPDS, primarily its LGP implementation. A. Mermoud et al. [13, 24] in a prospective study report on the effectiveness of LGP in 41% of cases, which immediately increases the hypotensive success of the NPDS in 83% of observed cases at 1 year. In a large retrospective study, Y. Lachkar et al. [25] report performing LGP in 47.3% of cases. Similarly, M. Detry-Morel and M. Detry [26] reported about 63% of patients reaching IOP level of 15 mm Hg after and LGP. However, the timing of LGP and the follow-up period were not specified. D. Tam et al. [20] reported a decrease in IOP from 20.2 to 11.7 mm Hg after LGP performed within 12.4±10 months after NPDS. Therefore, most of the publications confirm the need for Nd:YAG LGP after NPDS. In addition, the recommendations of T. Shaarawy et al. no longer recognize Nd:YAG LGP as a complication or deficiency of NPDS [18].

The fundamental difference of the present study was the performance of Nd:YAG LGP in the absolute number of patients, and it being preventive and in the established early periods after surgery in the 2nd group. As demonstrated by the results of the study, early Nd:YAG LGP is a safe and effective procedure with a low incidence of complications such as inflammation, hemorrhage and CCD. Despite the limitations of the study, it should be noted that LGP performed 3.46±1.9 (1.5-6.7) months after surgery required a greater number of postoperative interventions (p=0.03) **(see Table 1)**. As shown by the retrospective stage of the study, patients in the control group needed adjuvant procedures (transpalpebral massage, suturolysis, needling, etc.) more often and the appointment of prolonged anti-inflammatory therapy, including 0.1% dexamethozone for 6–8 weeks using a decreasing regimen (1 drop 5 times a day for 2 weeks, 1 drop 4 times a day for 2 weeks, 1 drop 3 times a day for 2 weeks, 1 drop 2 times a day for 2 weeks) and 0.09% bromfenac for 1 month (one-time or transition to it), taking into account the additive anti-inflammatory effect of the combined use of these drugs [17, 27, 28]. Ultimately, preventive LGP excluded additional resistance to IOF outflow in the TDM area and showed a significant high hypotensive effectiveness of NPDS with early Nd:YAG LGP according to the criterion of "complete" hypotensive success (p=0.001) **(Fig. 3)**. It is important that preventive Nd:YAG LGP and transformation of TDM into a microfistula in the early postoperative period did not change the philosophy of non-penetrating glaucoma surgery in general [1, 11, 12, 20]. In addition, in the presence of a microfistula in the TDM area , the development of signs of inadequate reparative regeneration at the level of ISC and/or FB can be regarded as a process independent of the state of TDM, characteristic of all fistulizing interventions and requiring appropriate rehabilitation measures.

To summarize, TDM plays a key role in the formation of IOF outflow pathways after NPDS. Performing Nd:YAG LGP in the early postoperative period proved to be an effective and safe adjuvant option in an absolute number of cases that helped increase the long-term hypotensive effect of NPDS.

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Drafting of manuscript: N.V.
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The authors declare that there are no conflicts of interest.

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