

# INNOVATIVE APPROACHES USING LASER AND PHOTODYNAMIC THERAPY FOR MANAGING PURULENT-NECROTIC COMPLICATIONS IN THE LOWER LIMBS OF DIABETIC PATIENTS

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**Resume:** The article presents the results of clinical studies on the use of laser and photodynamic therapy in the treatment of purulent-necrotic processes of the lower extremities in patients with diabetes mellitus. For this purpose, the authors conducted clinical studies involving 110 patients who underwent surgery in the department of purulent-septic surgery at the ASMI clinic. The studies demonstrated that after the opening of purulent-necrotic lesions in the lower extremities of diabetic patients, the use of laser therapy in combination with photosensitization led to accelerated regression of inflammatory infiltration, complete cessation of purulent-necrotic discharge, wound cleansing, and activation of regeneration processes.

**Keywords:** diabetic phlegmon, autopsy of the purulent-necrotic process, photosensitization, laser irradiation.

# Relevance

Diabetes mellitus (DM) is a significant public health issue, affecting approximately 424.9 million people worldwide, with one-third of them being over 65 years old. Patients with DM are more prone to infections with a negative progression, resulting in higher morbidity and mortality compared to the general population. Infections localized in the soft tissues (skin, fascia, aponeuroses, subcutaneous tissue, muscles) in DM patients require a multidisciplinary approach, where aggressive surgical intervention is complemented by metabolic stabilization and prolonged antibacterial therapy. Among the various complications of DM, purulent processes in soft tissues are among the most challenging. Purulent conditions (abscesses, phlegmons, boils, carbuncles, hidradenitis, etc.) develop in 10-25% of DM patients. The spread of infection in DM can occur rapidly, where a small ulcer or wound can quickly escalate into severe phlegmon and sepsis within days. Treatment of diabetic phlegmon should be immediate, focusing on the removal of purulent-necrotic tissue and preventing further spread of the inflammatory process. The surgical approach aims at rapid recovery by excising necrotic tissue, eliminating purulent accumulation, and ensuring proper drainage. Various methods and wound dressings have been developed for local treatment of extensive and chronic non-healing wounds. However, the diversity of these treatments suggests that an ideal method for managing such wounds in DM has not yet been established, highlighting the need for ongoing research in this area. Therefore, clinical studies focused on developing new treatment methods for purulent-necrotic lesions of the soft tissues in the lower extremities in DM remain highly relevant in both purulent surgery and medicine overall.

The aim of this study is to enhance the treatment outcomes of purulent-necrotic lesions in the lower extremities of patients with diabetes mellitus through the application of photodynamic



therapy combined with laser radiation.

### Material and methods.

The clinical study spanned from 2020 to May 2023 and included 110 patients who underwent surgery in the purulent septic surgery department of the ASMI clinic for phlegmon of various localizations in the lower extremities, which developed against the background of diabetes mellitus (DM). The patients were divided into two groups. The main group consisted of 53 patients treated from 2022 to May 2023, in whom surgical treatment of lower extremity phlegmon was performed using an improved method for managing purulent-necrotic processes in patients with DM. The comparison group included 57 patients treated from 2020 to 2021, whose surgical treatment followed the traditional method. Both groups were comparable in key parameters such as gender, age, localization, and severity of the purulent-necrotic process.

The distribution of patients according to the localization of phlegmon in the lower limbs showed that in the comparison group, 24 (42.1%) patients had a purulent-necrotic process in the thigh and lower leg, while in 9 (15.8%) cases, the lesion was in the knee area. In the main group, 22 (41.5%) patients had femoral phlegmon, 8 (15.1%) in the lower leg, and 23 (43.4%) in the lower leg region

In both groups, men predominated, making up 73.7% (42 patients) in the comparison group and 69.8% (37 patients) in the main group. The patients' ages ranged from 18 to 70 years, with the majority being between 40 and 70 years old – 82.5% (47 patients) in the comparison group and 81.1% (43 patients) in the main group

Table 2 presents the factors that led to the development of phlegmon in the lower extremities. In more than a third of the patients, the initial trigger was acute inflammatory diseases of the skin and subcutaneous tissue (furuncle, carbuncle, pyoderma), while in about 20% of the cases, open or closed traumatic injuries of the skin and deeper tissues were the cause of the phlegmon. Other contributing factors included acute vascular and lymphatic conditions (acute thrombophlebitis, acute lymphadenitis, lymphangitis), microtraumas (wounds, abrasions, scratches, cracks), post-burn wounds (chemical or physical), and bite wounds.

Upon admission, all patients reported symptoms such as fever, general intoxication, redness and swelling at the site of the purulent-necrotic process, as well as softening of the infiltrate leading to the development of a purulent cavity. In the comparison group, 42 patients (73.7%) and 45 patients (84.9%) in the main group reported chills. Approximately 10% of the patients in both groups also noted lymph node enlargement

Depending on the type of phlegmon, the distribution showed the following. In the comparison group, 21 (36.8%) patients and in the main group, 17 (32.1%) had purulent phlegmon, serous in 6 (10.5%) and 4 (7.5%) patients, respectively, putrefactive in 7 (12.3%) and 7 (13.2%), necrotic in 13 (22.8%) and 16 (30.2%), anaerobic in 10 (17.5%) and 9 (17.0%) patients (Table 1).

Table 1

The distribution of patients with purulent-necrotic processes in the soft tissues of the lower extremities among patients with diabetes mellitus can be categorized based on the type of phlegmon. Typically, phlegmons in diabetic patients are classified into several types, including:



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Type of phlegmon	Comparison group (n=57)		Main group (n=53)	
	Amount	%	Amount	%
Serous	6	10,5%	4	7,5%
Purulent	21	36,8%	17	32,1%
Putrid	7	12,3%	7	13,2%
Necrotic	13	22,8%	16	30,2%
Anaerobic	10	17,5%	9	17,0%

After a short preoperative course of examination and preparation, all patients were operated on. An autopsy of a purulent-necrotic focus was performed, with necrectomy, while, as mentioned above, the wound management technique differed in the comparison groups.

At the stage of preoperative examination, the following methods were mainly carried out: Standard clinical research methods; clinical and laboratory methods; instrumental methods (ultrasound, ultrasound and tomographic methods according to indications); determination of the degree of intoxication; assessment of local status; sowing of wound discharge on microflora; bacteriological determination of sensitivity to antibiotics; radiography of the affected area according to indications; indications of CT, MRI of soft tissues; according to indications, other additional methods of investigation

### **RESULTS AND DISCUSSION**

### Assessment of the dynamics of the wound process after surgery

In both groups, the autopsy and sanitation of the hearth were identical in technical terms. The differences were in addition in the main group of methods of physical impact on the wound, that is, laser irradiation and the photodynamic effect of methylene blue.

# The technique of wound rehabilitation using laser therapy in combination with photosensitization

The goal is to enhance antibacterial efficacy and shorten the treatment duration for purulent-necrotic processes of the lower extremities in diabetic patients. This objective is achieved by applying a surgical treatment method that includes excision and debridement of necrotic tissues, placement of dual-lumen drains, sealing the wound from external contamination using a sterile self-adhesive polyethylene film (dressing film), followed by antiseptic procedures. In the postoperative phase, antiseptic treatment involves continuous wound cavity irrigation through the drains using a 0.1% methylene blue solution for 1 hour, administered under pressure of at least 500 mm H<sub>2</sub>O at a rate of 60 drops per minute. After 30 minutes of irrigation, the wound area is exposed to laser irradiation using the Vostok-2 device in a defocused continuous mode within the 630-660 nm wavelength range, with a power output of 120 MW, for 1 minute per 2.5-3.0 cm<sup>2</sup> of the treated area. This combination of methylene blue irrigation and laser therapy is carried out 3-4 times daily for 3-5 days, followed by twice daily for 2-3 days, and then once daily for an additional 2-3 days.

### Advantages of the method:

- requires less bandages, is not burdensome and painless for the patient;

- constant irrigation of the wound leads to the leaching of necrotic tissues and pus;

- methylene blue, being an antiseptic, under the action of laser radiation becomes a donator of oxygen radicals, providing a photodynamic effect that is detrimental to all types of pathogenic



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microflora.

## The method includes the following steps:

- dissection of tissues and sanitation of purulent congestion, excision of necrotic tissues with the leaving of two-light transparent drainage tubes in pockets and cavities;

- after removing the drains, the open wound is closed with a sterile polyethylene selfadhesive film, namely, a sterile Hydrofilm Hartmann adhesive film is glued in such a way that the film overlaps on the edges of the unchanged skin, with the sticky side to the wound, to create tightness;

- then, in the postoperative period, drip washing of the wound cavity is carried out through the installed drainage with 0.1% methylene blue solution for 1 hour under a pressure of at least 500 mm of water at a rate of 60 drops per minute, and 30 minutes after the start of washing through a film fixed over the wound, the wound area is irradiated with an Vostok-2 laser device in unfocused continuous mode, in the range of 630-660 nm, with a power of 120 MW, for 1 minute for each 2.5-3.0 cm2;

- this procedure is carried out 3-4 times a day for 3-5 days;

- after the acute purulent inflammation subsides, on average after 3-5 days, the procedure is carried out 2 times a day for 2-3 days and then 1 time a day for another 2-3 days.

Laser irradiation combined with wound washing is typically performed daily until the wound is fully cleansed and granulation tissue appears. On average, this treatment lasts 7-10 days, with 17-25 procedures conducted during this period. In the early postoperative phase, all potential complications were carefully monitored. The overall complication rate in the comparison group was 66.7% (38 out of 57 patients), while in the main group, only 24.5% (13 out of 53 patients) experienced complications, a statistically significant reduction ( $\chi 2=19.610$ ; df=1; p<0.001). The extent of the initial lesion influenced its potential spread after debridement, which was observed in both groups. However, additional treatment in the main group effectively reduced the risk of this complication by a factor of four. Specifically, the spread of inflammation to adjacent tissues occurred in 21 (36.8%) patients in the comparison group versus 5 (9.4%) in the main group. Marginal wound necrosis was seen in 15 (26.3%) and 6 (11.3%) patients, respectively. Hemorrhage and wound infiltration were also common in the comparison group, affecting 9 (15.8%) patients, whereas in the main group, infiltration developed in only 3 (5.7%) patients. Acute lymphangitis occurred in 6 (10.5%) and 2 (3.8%) patients, respectively.

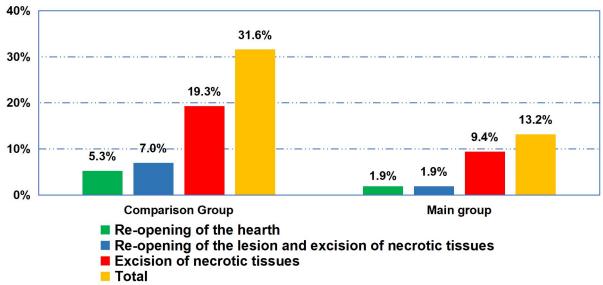
The development of complications after opening purulent-necrotic lesions in diabetic patients required appropriate additional interventions. For cases involving hemorrhage from the surgical wound, treatment was limited to tamponade with a hemostatic sponge and administration of hemostatic agents; these issues generally arose within 1-2 days post-surgery. In situations where the purulent process spread (purulent congestion), additional surgeries were performed to drain the infection, often requiring secondary wound treatment through an additional incision. These complications typically manifested 2-3 days post-surgery.

In cases of postoperative wound infiltration, conservative management was applied, including physiotherapy, anti-inflammatory therapy, and local treatments, with these complications generally arising between days 5-7. When necrosis of the wound edges was present, excision of the necrotic tissue was the primary intervention. For acute lymphangitis, a



combination of conservative measures, including anti-inflammatory and antibacterial treatments, antihistamines, and physiotherapy (ultraviolet therapy), was employed. This complication typically coincided with the peak of the inflammatory process due to lower limb phlegmon and persisted into the early postoperative period.

Overall, additional invasive procedures were necessary in 18 (31.6%) patients in the comparison group, whereas only 7 (13.2%) patients required such interventions in the main group ( $\chi 2=5.278$ ; df=1; p=0.022). Repeat surgery for the spread of inflammation was conducted in 3 (5.3%) and 1 (1.9%) patients, respectively. In 4 (7.0%) and 1 (1.9%) cases, this involved excision of necrotic tissues. In 11 (19.3%) and 5 (9.4%) cases, treatment was limited to necrotic tissue excision (see Fig. 1).

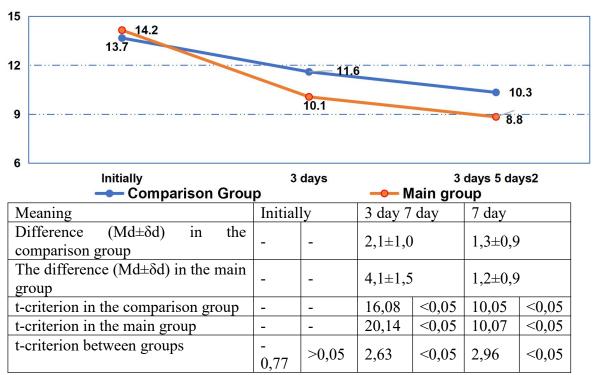




In the early postoperative period following the incision of purulent-necrotic lesions, the assessment of the local wound status was conducted dynamically based on skin condition surrounding the wound (including color), presence of edema, hyperemia, purulent swelling, necrotic tissue, local temperature, as well as the nature and size of the wound defect.

The focus first turns to the dynamics of leukocytosis. Both groups showed a regression in leukocytosis during the early postoperative period. In the comparison group, the preoperative leukocyte count was  $13.7\pm3.7 \times 10^{9}/l$ , which decreased to  $11.6\pm3.5 \times 10^{9}/l$  by day 3 (t=16.08; p<0.05) and further reduced to  $10.3\pm3.1 \times 10^{9}/l$  by day 7 (t=10.05; p<0.05). Meanwhile, in the main group, the preoperative leukocyte level was  $14.2\pm2.8 \times 10^{9}/l$ , which dropped to  $10.1\pm2.6 \times 10^{9}/l$  by day 3 (t=20.14; p<0.05) and to  $8.8\pm2.1 \times 10^{9}/l$  by day 7 (t=10.07; p<0.05). Significant differences in leukocyte levels were observed between the groups both on day 3 (t=2.63; p<0.05) and day 7 (t=2.96; p<0.05) (see Fig. 2).



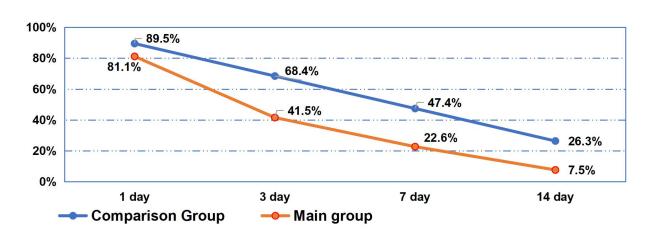


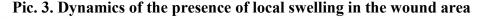
## Pic. 2. Dynamics of blood leukocyte indices (x109/l) in comparison groups (M±δ)

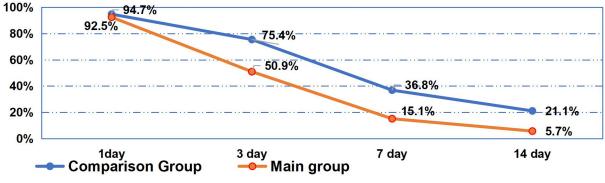
The next factor in assessing the quality of the course of the wound process was the regression of local swelling. On the first day, swelling in the wound area persisted in 51 (89.5%) patients in the comparison group and 43 (81.1%) in the main group ( $\chi 2=1.537$ ; df=1; p=0.216). On day 3, this factor was determined in 39 (68.4%) and 22 (41.5%) patients, respectively, while the indicators significantly differed in the main group ( $\chi 2=8,052$ ; df=1; p=0.005). On day 7, swelling persisted in 27 (47.4%) patients in the comparison group and only in 12 (22.6%) patients in the main group ( $\chi 2=7,338$ ; df=1; p=0.007), and on day 14 in 15 (26.3%) and 4 (7.5%) patients ( $\chi 2=6,770$ ; df=1; p=0.010) (Pic. 3).

Next, we present data on the regression of hyperemia. On the first day, hyperemia in the wound area was in 54 (94.7%) patients in the comparison group and 49 (92.5%) in the main group ( $\chi 2=0.240$ ; df=1; p=0.624). On day 3, this factor was determined in 43 (75.4%) and 27 (50.9%) patients, respectively, while the indicators significantly differed in the main group ( $\chi 2=7,121$ ; df=1; p=0.008). On day 7, hyperemia persisted in 21 (36.8%) patients in the comparison group and only in 8 (15.1%) patients in the main group ( $\chi 2=6.691$ ; df=1; p=0.010), and on day 14 in 12 (21.1%) and 3 (5.7%) patients ( $\chi 2=5,525$ ; df=1; p=0.019) (Pic. 4).



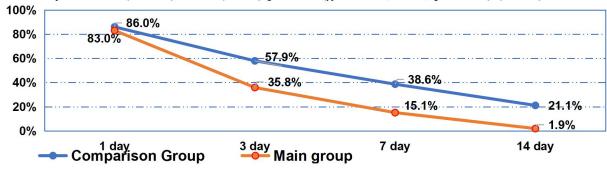


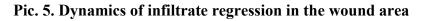






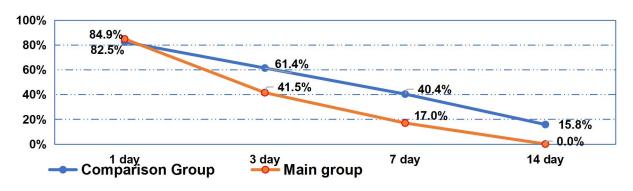
Next, we present data on the regression of wound infiltration. On the first day, infiltration in the wound area was in 49 (86.0%) patients in the comparison group and 44 (83.0%) in the main group ( $\chi 2=0.182$ ; df=1; p=0.624).On day 3, this factor was determined in 33 (57.9%) and 19 (35.8%) patients, respectively, while the indicators significantly differed in the main group ( $\chi 2=5,355$ ; df=1; p=0.021).On day 7, infiltration persisted in 22 (38.6%) patients in the comparison group and only in 8 (15.1%) patients in the main group ( $\chi 2=7,648$ ; df=1; p=0.006), and on day 14 in 12 (21.1%) and 1 (1.9%) patients ( $\chi 2=9.680$ ; df=1; p=0.002) (Pic. 5).

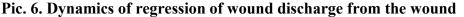




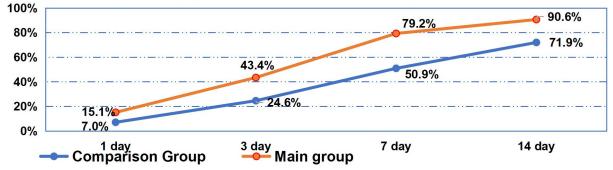


On the first day, purulent wound discharge from the wound was in 47 (82.5%) patients in the comparison group and 45 (84.5%) in the main group ( $\chi 2=0.120$ ; df=1; p=0.729).On day 3, this factor was determined in 35 (61.4%) and 22 (41.5%) patients, respectively, while the indicators significantly differed in the main group ( $\chi 2=4,354$ ; df=1; p=0.037).On day 7, the discharge was in 23 (40.4%) patients in the comparison group and only in 9 (17.0%) patients in the main group ( $\chi 2=7,271$ ; df=1; p=0.008), and on day 14 in 9 (15.8%) and was absent in patients in the main group ( $\chi 2=9,114$ ; df=1; p=0.003) (fig. 6).





One of the main criteria is the timing of complete cleansing of the wound. This factor was determined on day 3 in 11 (20.8%) patients in the main group ( $\chi 2=13.145$ ; df=1; p<0.001).By day 7, the wound was cleared in 14 (24.6%) patients in the comparison group and in 29 (54.7%) patients in the main group ( $\chi 2=10.489$ ; df=1; p=0.002), and on day 14 in 36 (63.2%) and 48 (90.6%) patients, respectively ( $\chi 2=9,196$ ; df=1; p=0.003) (Pic. 7).



Pic. 7. The proportion of patients with wound cleansing in dynamics

The introduction of a new treatment method for purulent-necrotic processes in the lower extremities of patients with diabetes mellitus resulted in a substantial decrease in postoperative complications, dropping from 66.7% (observed in 38 out of 57 patients in the comparison group) to 24.5% (in 13 out of 53 patients in the main group;  $\chi 2=19.610$ ; df=1; p<0.001). This change also led to a reduction in the need for repeat surgeries, which fell from 31.6% (18 patients in the comparison group) to 13.2% (7 patients in the main group;  $\chi 2=5.278$ ; df=1; p=0.022). By stimulating the etio-pathogenetic mechanisms involved in purulent wound healing, the regression of the wound process was significantly accelerated. Specifically, by day 3, leukocytosis levels



had significantly decreased (from  $13.7\pm3.7$  to  $11.6\pm3.5 \times 109/1$  in the comparison group and from  $14.2\pm2.8$  to  $10.1\pm2.6 \times 109/1$  in the main group; t=2.63; p<0.05). Additionally, by day 7, wound edema persisted in 36.8% (21 patients) in the comparison group compared to 15.1% (8 patients) in the main group ( $\chi 2=6.691$ ; df=1; p=0.010), infiltration was present in 38.6% (22 patients) versus 15.1% (8 patients) ( $\chi 2=7.648$ ; df=1; p=0.006), and wound discharge was observed in 40.4% (23 patients) versus 17.0% (9 patients) ( $\chi 2=7.271$ ; df=1; p=0.008). At the same time, complete wound cleansing was achieved in 50.9% (29 patients) in the comparison group comparison group comparison group in 24.6% (14 patients) versus 54.7% (29 patients) ( $\chi 2=10.489$ ; df=1; p=0.002).

### CONCLUSIONS

1. The implementation of a novel method for managing purulent-necrotic processes in the lower extremities of patients with diabetes mellitus has led to a significant reduction in postoperative complications from 66.7% to 24.5% (p<0.001), thereby lowering the necessity for repeat surgeries from 31.6% to 13.2% (p=0.022). By the 7th day, notable improvements were observed, including a marked decrease in leukocytosis ( $10.3\pm3.1$  vs.  $8.8\pm2.1$  x109/l; p<0.05), a drop in the proportion of patients with persistent edema from 36.8% to 15.1% (p=0.010), infiltration from 38.6% to 15.1% (p=0.006), and wound discharge from 40.4% to 17.0% (p=0.008). Additionally, there was an increase in patients with fully cleansed wounds from 50.9% to 79.2% (p=0.002) and in those showing granulation tissue formation from 24.6% to 54.7% (p=0.002).

2. Stimulating the etio-pathogenetic mechanisms of purulent wound healing significantly accelerated wound process regression. The frequency of complete wound epithelization by the 14th day of treatment rose from 36.8% to 69.8% (p<0.002), while a substantial reduction in wound surface area (p<0.05) was noted. The average time to full wound healing decreased from  $19.1\pm10.3$  to  $12.5\pm6.3$  days (p<0.05), alongside a reduction in hospitalization duration from  $11.2\pm4.1$  to  $8.3\pm2.7$  days (p<0.05).

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