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Comparative Efficacy of Microdacyn and Dioxidin in Patients with Diabetic Foot Syndrome

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ABSTRACT

Background. Diabetic foot syndrome is the main cause of hospitalization and mortality in patients with diabetes mellitus, of which 25% have purulent-necrotic lesions of the feet during their lives.

Material and methods. The results of the treatment of 116 patients with diabetic foot syndrome who were treated and examined in the Department of Surgical Infection of the Multidisciplinary Clinic of the Tashkent Medical Academy are analyzed. Evaluation of the results of treatment of patients with purulent-necrotic processes of diabetic foot syndrome was carried out, first of all, on the basis of a study of the general condition of patients and data from the local course of the process.

Results. The combined use of Microdacyn in the complex treatment of diabetic foot syndrome in phase I of the wound process leads to a decrease in microbial contamination, faster completion of the stages of inflammation, and optimizes the processes of reparative tissue regeneration.

Conclusion. The proposed method can be used as a preoperative preparation of purulent-necrotic wounds in patients with diabetic foot syndrome to the final method of closure with the use of plastic surgery.

Keywords: Diabetic foot syndrome, Microdacyn, Dioxidin, comparative evaluation of efficacy

INTRODUCTION

The problem of diabetes mellitus treatment remains relevant [1]. In terms of prevalence, this disease ranks third in the world after cardiovascular and oncological diseases [2]. Every year, the number of patients with this pathology increases by 5-7% [3].

The great social significance of diabetes mellitus lies in the fact that this disease leads to early disability and mortality due to complications, including diabetic foot syndrome, identified in 1987 by the World Health Organization as an independent nosological complication along with damage to the eyes, kidneys, nervous and cardiovascular systems, occupies a leading position [4].

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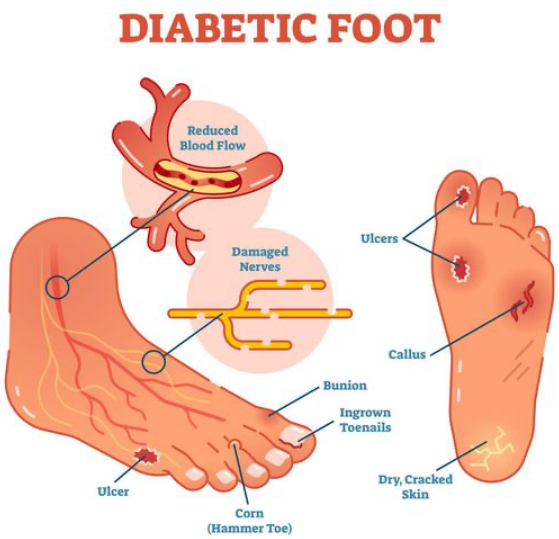
Diabetic foot syndrome is formed as a result of diabetic micro- and macroangiopathy, neuropathy and osteoarthropathy with further addition and progression of surgical infection [5].



The risk of developing diabetic foot syndrome increases with age and the duration of diabetes mellitus. The risk of gangrene in patients with diabetes mellitus is 6 times higher than in the rest of the population of patients with vascular pathology (obliterating atherosclerosis of the vessels of the lower extremities, nonspecific aortoarteritis, and others) [6].

Mortality rates within 1 year after amputation are 11-41%, within 3 years - 20-50%, and within 5 years - 39-68% [7]. Death after amputation is most often caused by concomitant pathology of the cardiovascular system and kidneys [8].

The unacceptably high level of amputations in diabetic foot syndrome, the limited possibilities of vascular surgical methods of treatment and the lack of effective regimens for conservative therapy of this pathology make it increasingly important to search for new methods of treatment and schemes of complex local corrective effects, especially those drug factors that have a regenerative orientation to the processes of reparative histogenesis [9].

However, to date, there is no data on the therapeutic use of Microdacyn in the complex treatment of diabetic foot syndrome [10].

MATERIAL AND METHODS

The study covers 116 patients with purulent-necrotic processes of diabetic foot syndrome. There were 38 (32.8%) males and 78 (67.2%) females. The age of the patients ranged from 38 to 82 years. All patients suffered from type II diabetes mellitus. The duration of diabetes mellitus ranged from several months to 34 years. Among the concomitant pathology in the studied patients, lesions of the cardiovascular system prevailed.

All patients underwent examination, including general thermometry, electrocardiography, clinical blood and urine tests, biochemical studies for total protein, bilirubin, urea, cholesterol, blood sugar, radiography of the extremities, ultrasound examination of soft tissues, blood vessels, transcutaneous determination of oxygen tension in the first interdigital space.

In all patients, according to indications, complex treatment was carried out, including correction of carbohydrate metabolism, antioxidants, antibiotics, immunoprotective, detoxification therapy, B vitamins, symptomatic treatment, disaggregates, anti-sclerotic drugs, antispasmodics, drugs that affect microcirculation. In some patients, purulent wounds were prepared for plastic surgery (secondary sutures, autodermoplasty).

All patients were divided into 3 randomized groups. The main group included 56 patients with purulent-necrotic processes of diabetic foot syndrome. It consisted of two subgroups: the first subgroup (37 patients) - with purulent-necrotic processes of soft tissues; and the second (19 patients) - with purulent-necrotic complications after "small" and "large" amputations. In the first phase of the wound process in patients of the main group, Microdacyn was used.

In the first subgroup of 37 patients, 22 wounds were treated in an open way, and 15 underwent plastic surgery. In the second subgroup, consisting of 19 patients, 9 pa-

tients had purulent-necrotic wounds in an open way, and 10 patients underwent plastic surgery.

Fungal lesion of diabetic foot syndrome

Two control groups included 60 patients. In 30 patients of the first control group, only Microdacyn was used topically, in 30 patients of the second control group, a 1% solution of Dioxidin was used in the first stage of the wound process (before cleansing the wounds from purulent-necrotic contents), and sea buckthorn oil was used in the second stage of the wound process (after purification from purulent-necrotic contents).

In the first control group of patients treated topically with Microdacyn, two subgroups were distinguished: the first (16 patients) with purulent-necrotic processes of soft tissues and the second (14 patients) with purulent-necrotic complications after "small" and "large" amputations. Of the above-mentioned 16 patients of the first subgroup, 10 patients were treated in an open way, 6 patients underwent autodermoplasty. In the second subgroup, which included 14 patients, 9 patients treated wounds in an open way, and 5 patients received secondary sutures.

In the second control group of patients, in the treatment of which a 1% solution of Dioxidin and sea buckthorn oil was used at different stages of the wound process, two subgroups were also distinguished: the first (14 patients) - with purulent-necrotic processes of soft tissues and the second (16 patients) - with purulent-necrotic complications after "small" and "large" amputations. Of these 14 patients of the first subgroup, 8 patients had open wounds, and 6 patients underwent autodermoplasty. In the second subgroup, which included 16 patients, 9 patients had open wounds, 7 patients underwent plastic surgery (3 patients underwent autodermoplasty, 4 patients underwent secondary sutures).

Analyzing the methods of treatment used in patients of the control groups, it can be said that the open method of wound management was used in 36 patients of both control groups. Of these, in 19 patients, local treatment included only Microdacyn, in 17 - 1% solution of Dioxidin and sea buckthorn oil at different stages of the wound process.

Of the 24 patients in the control groups who underwent plastic surgery, Microdacyn was used topically in 11 patients, 1% Dioxidin solution and sea buckthorn oil in 13 patients.

All patients with purulent-necrotic processes of diabetic foot syndrome of the main and control groups underwent radical removal of non-viable tissues under general or local anaesthesia, then patients underwent daily dressings, during which, after skin treatment, loose purulent-necrotic masses were removed from the wound. The treatment of the wound surface was carried out using a 3% solution of hydrogen peroxide. Further, the patients of the main group in the first phase of the wound process were exposed to ultraviolet irradiation of the affected limb every other day, in the second phase of the wound process, currents above the tonal frequency were used.

Stages of ulcerative process development

When applying early secondary sutures to the wound, patients of the main and control groups were injected with a rubber graduate or polyvinyl chloride tubes for the outflow of wound discharge for several days. Every day after the secondary sutures, dressings with Microdacyn continued to be done, and in the second control group - with sea buckthorn oil. All patients received antibiotics after suturing. Early secondary sutures were applied with a satisfactory general condition of the patient, normalization of temperature, peripheral blood composition, glycemia level, the disappearance of edema and hyper-

emia around the wound, it's complete cleansing from purulent-necrotic masses and the appearance of juicy granulations. The stitches were removed for 10-12 days.

Ulcers in diabetic foot syndrome

With pronounced decompensation of diabetes, surgery was postponed, taking the necessary measures to combat acidosis and hyperglycemia. Only with the elimination of ketonuria, a decrease in blood sugar levels below 11.8 mmol/l, and an improvement in the patient's condition, an operation was performed. In the postoperative period, regardless of the severity of diabetes, simple insulin was prescribed fractionally, 4-6 times a day, under the control of the glycemic and glucosuric profile. Full compensation for diabetes with the normalization of blood sugar to normal and the disappearance of glucosuria was not our goal.

Monitoring of the general condition of patients was carried out using indicators such as well-being, sleep, and appetite. Instrumental and laboratory data were used: general thermometry, electrocardiography, clinical blood and urine tests, and biochemical blood tests (total protein, urea, creatinine, bilirubin, sugar, chlorides). Clinical analyses and biochemical blood tests were carried out in accordance with generally accepted recommendations.

The dynamics of the course of the wound process were determined by the following clinical signs: the timing of the disappearance of infiltration and hyperemia of the wound edges, the nature and amount of wound discharge, the timing of cleansing wounds from purulent-necrotic contents, the timing of the appearance of granulations, marginal epithelialization and healing.

The study of the composition of the microflora of purulent wounds was carried out according to the generally accepted method in all patients of the main and control groups before the start of treatment, on days 7, 14, and 21 of treatment and before the end of therapy. The material was taken by smears, followed by bacterioscopy and bacteriological examination on the media: Endo, blood agar, meat-peptone agar, and thioglycol. On the basis of these methods, the species of the sown microflora was established. To determine the sensitivity of microflora to antibiotics, the paper disc method was used.

RESULTS

Studies have found that in all respects, the wound process proceeds most favourably in patients in the local treatment of which Microdacyn and physical methods of exposure were used at different stages of the wound process.

In most cases, on the 8th day of treatment, the wounds were cleansed of purulent-necrotic contents. By this time, the severity of inflammatory changes in the surrounding tissues significantly decreased. By the 10th day of treatment, the wound was contracted, and its bottom and walls were covered with juicy, bright red granulations, on average, by the 12th day of therapy, the onset of epithelialization was noted. The duration of inpatient treatment of patients averaged 24 days.

Fungal hyperkeratosis in diabetic foot syndrome

In patients of the first control group, changes similar to those in the main group occurred in the treatment of

wounds, but they occurred somewhat more slowly. Cleansing of wounds was observed on the 11th day of treatment, the appearance of granulations was observed on average on day 12, and marginal epithelialization - on day 15 of local use of Microdacyn. The duration of inpatient treatment of patients in the control group averaged 28 bed days.

In the second control group, wound cleansing was noted by the 13th day of treatment. However, complete cleansing of wounds from purulent necrotic masses did not occur. Swelling and flushing of the skin around the wounds decreased slightly. By this time, fine-grained, pale pink granulations appeared, in some places with signs of their swelling. The onset of epithelialization was detected by the 18th day of wound treatment.

On days 14 and 21, purulent contents were still noted in the wounds, albeit in smaller quantities. The perifocal inflammatory process also persisted. By day 21, there was a convincing decrease in the size of the wounds, they were performed with pink granulations, and the perifocal inflammatory process was noticeably declining. The duration of inpatient treatment averaged 39 days.

Improvement of the general condition, reduction of pain in the affected limb, decrease in body temperature to normal in patients of the main group occurred after 4.2±0.3 days of treatment, in patients treated only with Microdacyn - after 5.5±0.1 days, in patients in the treatment of which a 1% solution of Dioxidin and sea buckthorn oil was used - after 9.8±0.3 days of treatment ($p<0.05$). On average, the duration of treatment of purulent-necrotic wounds of the foot in patients of the main group is 1.2 times less than in patients of the first control group, and 1.7 times less than in patients of the second control group.

Thus, the most favorable results of complex conservative treatment of purulent-necrotic wounds in patients with diabetic foot syndrome were achieved with the combined local use of Microdacyn, ultraviolet irradiation in the first phase of the wound process, Microdacyn and currents over the tonal frequency in the second phase of the wound process.

Microdacyn and physical methods of exposure have also been successfully used to prepare purulent wounds in patients with diabetic foot syndrome for plastic surgery: early secondary sutures, and autodermoplasty.

A favorable outcome occurred in 7 patients of the main group who underwent early secondary sutures and in 18 patients who underwent autodermoplasty. For the purpose of comparison, 5 patients of the first control group and 4 patients of the second control group also underwent early secondary sutures; 6 patients of the first control group, and 9 patients of the second control group underwent autodermoplasty.

The duration of preparation of purulent-necrotic wounds in patients with diabetic foot syndrome of the main group for the imposition of early secondary sutures and autodermoplasty was significantly less ($p<0.05$) than in the control groups.

In the main group, the duration of the preoperative period before the application of early secondary sutures compared to the first control group was 1.3 times less, with the second control group - 1.8 times. The duration of inpatient treatment in patients of the main group with the imposition of early secondary sutures is less than that in patients of the first control group - 1.2 times, the second control group - 1.5 times.

The preoperative period before autodermoplasty in the main group is 1.3 times less than in patients of the first control group and 1.6 times less in patients of the second control group. The duration of inpatient treatment with the use of autodermoplasty in patients of the main group is less than in patients of the first control group - 1.2 times and 1.5 times than in the second control group.

The method of plastic surgery (early secondary sutures or autodermoplasty) was chosen individually depending on the area and depth of the wound, the characteristics of the course of the purulent-inflammatory process. After autodermoplasty in all 18 patients of the main and 6 patients of the first control group, excellent and good results were obtained. And in 2 out of 9 patients of the second control group, satisfactory results were obtained.

Clinical data indicating a more pronounced effect of the combined topical application of Microdacyn, ultraviolet radiation in the first phase of the wound process, Microdacyn and currents above the tonal frequency in the second phase of the wound process on the healing of purulent-necrotic wounds of the foot in patients with diabetic foot syndrome compared with the use of Microdacyn alone and especially 1% solution of Dioxidin and sea buckthorn oil, were confirmed by microbiological studies.

Before the start of treatment, the microflora was sown from the wounds of all patients, and 76.4% of microbes were isolated in monoculture.

On day 7 of topical treatment with Microdacyn in combination with ultraviolet irradiation, the microflora was not seeded from wounds in 11 patients (35%) out of 31.

Among the patients of the first control group, on the 7th day of treatment, microflora from wounds was not distinguished in 5 patients out of 19 (26%); Among the patients of the second control group, microflora was not detected in 2 out of 17 patients (12%).

By the end of treatment, microflora from wounds was not isolated in 21 patients out of 31 (68%) in the main group, in 9 patients out of 19 (47%) in the first control group, and only in 3 patients (18%) out of 17 patients in the second control group.

Our histological analysis of the studied intraoperative excisive objects (at the light-optical and ultrastructural levels) showed that, in general, morphological changes in the tissue elements of ulcerative foot defects in patients with diabetic foot syndrome fully fit into the picture of the traditional course of the purulent-necrotic process. The main element here is the formation of pustule cavity elements filled with granulocytes and decaying cells that capture the deep layers of the dermis and hypodermis.

Pustules affect not only the epidermis, but also the papillary layer of the dermis, hair follicles and sebaceous glands. The epidermis, on the other hand, is in a state of acanthosis with symptoms of severe intercellular edema, hyperkeratosis, and sometimes parakeratosis. In areas of purulent inflammation, signs of hemorrhagic vasculitis are recorded, indicating damage to hemocapillaries such as fibrinoid necrosis.

A significant part of arterioles, venules and hemocapillaries in biopsy specimens are necrotic, perivascular infiltrate contains mainly neutrophilic granulocytes with a small admixture of eosinophils. At the same time, neutrophil karyorexis is very characteristic. Against the background of severe oedema and fibrinoid changes in the collagen substance of the dermis, extensive haemorrhages were identified.

Electron microscopy revealed pronounced intracellular and intradermal edema of epidermocytes, fibroblasts, endothelial cells, a significant number of large mitochondria in epidermocytes with dystrophic changes.

DISCUSSION

Tonofibrils and clumps of keratohyalin in the granular layer are not detected, which indicates a sharp hypoxia of epidermocytes [11].

Tonofilaments - in various stages of "edematous" dystrophy [12]. The dermoepidermal zone of the wound area is characterized by loosening with the formation of defects through which subepidermal cells penetrate from the dermis into the epidermis [13].

At the same time, such classical signs of inflammation as exudation and proliferation are poorly expressed against the background of necrotic changes in epithelial, connective tissue structures and vessels of the microvasculature [14]. The latter have always had signs of microthrombosis and ultrastructural damage to endothelial cells [15]. This manifested itself in the "balloon" vesiculation of the tubules of the endoplasmic reticulum, the disorganization of the membrane compartments of endothelial cells, the appearance of liposomes and layered myelin-like bodies in their cytoplasm [16].

In this regard, our observations are consistent with the data of other researchers who interpret the described changes in the tissues of ulcers that occur in patients with diabetes mellitus as extremely unfavorable, leading to an aggravation of tissue acidosis under conditions of the suppurative process [17-22].

Our studies have shown that in patients of the second control group (locally treated with 1% Dioxidin solution and sea buckthorn oil) there is no effective correction of emerging disorders of tissue and cellular homeostasis, which does not subsequently provide adequate reparative regeneration of tissue structures. In particular, this concerned the weak (slow) development of granulation (poorly differentiated connective) tissue. The processes of fibrillogenesis were significantly disrupted against the background of a pronounced purulent process [23-29].

When Microdacyn was included in the complex of therapeutic measures in combination with physical methods of exposure, the zone of necrotic changes in the epidermis, its derivatives, and structures of the dermis and hypodermis decreased in comparison with those when using Microdacyn alone by 1.3±0.07 times and by 2.4±0.06 times when using a 1% solution of Dioxidin and sea buckthorn oil.

The formation of exudate and inflammatory cell infiltrate leads to the onset of proliferative processes of cells in accordance with their histo- and organoblastic potencies. Our studies have shown that under the conditions of using Microdacyn (especially in combination with physical methods), this stage, aimed at restoring damaged tissues, is usually associated with the activation of cambial (poorly differentiated) cells, accompanied by an increase in the number of lymphocytes and monocytes. At the same time, cellular differentiation of fibroblasts is observed in the focus of inflammation, and the number of plasma cells and macrophages increases.

At the same time, epithelial cells, endothelial and adventitial cells were mobilized for reproduction with the

formation of proliferates in the wound area [30]. Subsequent secondary differentiation is closely related to the rate of maturation of connective tissue. In this regard, it should be noted that the neoplasm and cytodifferentiation of the connective tissue elements of the wound were adequate homeostatic, that is, the epithelial regenerate repeats all histotypic signs of vertical anisomorphism [31].

It has been established that the use of Microdacyn and physical factors for therapeutic purposes leads to the formation of a pronounced heteromorphism of fibroblastic cells (poorly differentiated fibroblasts, young fibroblasts, mature collagen-forming forms, myofibroblasts, fibrocytes).

We interpret these data from the well-known positions of morphologists, as an indicator of the implementation by the tissue structures of the wound defect of their adaptive and compensatory capabilities, manifested under the influence of the chosen method of treating foot wounds (Microdacyn in combination with physical factors) [32].

The observed functional activity of macrophage and mast cells also indicated a positive effect on the repair of foot wounds of the combined factors used in the treatment of purulent-necrotic processes in patients with diabetes mellitus.

This conclusion follows from the fundamental provisions of tissue biology, convincingly proving that, along with plasma mediators of inflammation, pro-inflammatory factors produced by lymphocytes and macrophages control the realization of their regenerative capabilities by tissues. Obviously, this effect should be mediated through the production of chemotactic substances (and above all for cells that organize the "field" of inflammation), through the secretion of interleukins, interferons, leukotrienes, and various colony-stimulating (for granulocytes and monocytes) factors by macrophages [33-37].

Thus, the complex of therapeutic measures used significantly corrects impaired cellular and tissue homeostasis in patients, ensuring the creation of the necessary conditions for the realization of biological properties not only by fibroblastic different cells but also by macrophages.

On the basis of the light-optical and ultrastructural study of histopreparations of wounds of patients in whom Microdacyn was used, and especially in combination with physical factors of influence, more favorable conditions were always created for the development of granulation tissue and neovasculogenesis, which ultimately led to the effective healing of the wound defect.

CONCLUSION

On the basis of complex clinical, microbiological, morphofunctional studies of combined topical application of Microdacyn, their therapeutic efficacy for the healing of purulent-necrotic wounds in patients with diabetic foot syndrome has been established. It was found that in all respects, the wound process proceeds more favorably in patients with combined topical use of Microdacyn and physical methods than in patients treated with only 1% Dioxidin solution. The duration of treatment of patients with diabetic foot syndrome of the main group is 1.2 times less than those in patients treated only with Microdacyn, 1.7 times less than in patients who used a 1% solution of Dioxidin.

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Consent for publication - The study is valid, and recognition by the organisation is not required. The authors agree to open the publication.

Availability of data and material - Available

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DIABETIK OYOQ SINDROMI BILAN OG'RIGAN BEMORLARDA MIKRODASTIN VA DIOKSIDINNING SOLISHTIRMA SAMARADORLIGI

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ABSTRAKT

Dolzarbligi. Diabetik oyoq sindromi bilan og'ruvchi bemorlarda kasalxonaga yotqizish va o'limning asosiy sababi bo'lib, ulardan 25 foizida hayot davomida oyoqlarning yiringli-nekrotik kasallik mavjud.

Material va usullar. Toshkent tibbiyot akademiyasi ko'p tarmoqli klinikasining xirurgik infeksiyasi bo'limida 116 nafar diabetik oyoq sindromi bilan og'rilgan bemorlarni davolash natijalari tahlil qilinadi. Diabetik oyoq sindromining yiringli-nekrotik jarayonlari bilan og'rilgan bemorlarni davolash natijalarini baholash, birinchi navbatda, bemorlarning umumiy ahvolini o'rganish va jarayonning lokal ma'lumotlar asosida amalga oshirildi.

Natijalar. Yara jarayonining I bosqichida diabetik oyoq sindromini kompleks davolashda Microdacynning birgalikda qo'llanilishi mikroblar ifloslanishining pasayishiga, yallig'lanish bosqichlarini tezroq tugallanishiga olib keladi va reparativ to'qimalarni qayta tiklash jarayonlarini optimallashtiradi.

Xulosa. Taklif etilayotgan usul diabetik oyoq sindromi bilan og'rilgan bemorlarda plastik operatsiyani qo'llash bilan yopishning yakuniy usuliga yiringli-nekrotik yaralarni operatsiyadan oldingi preparat sifatida qo'llash mumkin.

Kalit so'zlar: Diabetik oyoq sindromi, Mikrodastin, Dioksidin, samaradorlikni qiyosiy baholash

СРАВНИТЕЛЬНАЯ ЭФФЕКТИВНОСТЬ ПРИМЕНЕНИЯ MICRODACYN И DIOXIDIN У БОЛЬНЫХ СИНДРОМОМ ДИАБЕТИЧЕСКОЙ СТОПЫ

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АБСТРАКТ

Актуальность. Синдром диабетической стопы - основная причина госпитализации и смертности больных с сахарным диабетом, из которых у 25% в течение жизни возникают гнойно-некротические поражения стоп.

Материал и методы. Анализируются результаты лечения 116 больных синдромом диабетической стопы, которые находились на лечении и обследовании в отделении хирургической инфекции Многопрофильной клиники Ташкентской медицинской академии. Оценка результатов лечения больных с гнойно-некротическими процессами синдрома диабетической стопы производилась, прежде всего, на основании изучения общего состояния пациентов и данных местного течения процесса.

Результаты. Комбинированное применение Microdacyn в комплексном лечении синдрома диабетической стопы в I фазу раневого процесса приводит к снижению микробной обсемененности, более быстрому завершению стадий воспаления, оптимизирует процессы репаративной регенерации тканей.

Заключение. Предлагаемый метод может быть использован в качестве предоперационной подготовки гнойно-некротических ран у больных синдромом диабетической стопы к окончательному методу закрытия с применением пластических операций.

Ключевые слова: Синдром диабетической стопы, Microdacyn, Dioxidin, сравнительная оценка эффективности